



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: 6.7 cents

Shares on issue: 351,337,149

Market cap: \$23.5 million

Chief executive officer: Paul McDonald

Board: Mark Simari (chair), Geoff Sam, Dr Jane Ryan

Financials (Half year to December 31 2022): revenue \$2.435 million (down 72%), net loss \$5.8 million (previous \$1.2 million profit), cash of \$4.3 million (down 53%) with \$7 million raised in June and July 2023

Major identifiable shareholders: Sandon Capital 16.6%, Regal Funds Management 12.99%

Two years ago, the drug manufacturing stalwart was in as good a position as it had ever been over a corporate lifetime spanning almost five decades.

With the nation engulfed in the pandemic, IDT seemed a shoo-in to host the first local production facility for messenger ribonucleic acid (mRNA) vaccines, which have a different mechanism of action to traditional prophylactics.

On the back of Victorian government support for developing a local mRNA vaccine, the Federal Health Department accorded 'readiness' status to IDT's mainstay facility at Boronia, in Melbourne's east.

Well, guess what? A flow-on contract never eventuated and the pandemic subsided (or, more accurately, politicians and the populace lost interest in the whole Covid thang).

Not for the first time, IDT has had to reinvent itself and under refreshed management it is targeting the emerging fields of mRNA and antibody drug conjugates, or ADCs, especially in oncology.

In the shorter term, IDT has deployed its Australian Therapeutics Goods Administration (TGA) -approved facility to prepare medical cannabis products, while it is also tapping the burgeoning demand for psychedelic drugs for research purposes.

Much of the revenue focus is on IDT's \$30 million sterile plant, which is suitable for making injectable drugs.

The facility had been mothballed, but has a new lease of life.

IDT history

Remember the 1960s?

Superannuated hippies 'researching' psychedelics at the time probably won't recall that IDT – as in Institute of Drug Technology - was founded in 1965 as a Victorian College of Pharmacy offshoot.

The entity became independent in October 1975 and developed a reputation for contract drug making and consulting work.

Under the renowned Dr Graeme Blackman, the company became private in 1982 and listed on the ASX in 1988.

In the 1990s, IDT moved to cytotoxic oncologic drugs. While this worked a treat for a while, generic versions took over and much of the production moved to China.

In 2014, IDT itself entered the US generics game, paying \$US18 million for a package of 23 drugs. A generics price war erupted and in 2018 IDT sold most of those assets for ... not much.

A specialist in aseptically processed parenteral* pharmaceuticals, Mr McDonald joined IDT two and a half years ago, having spent most of his career at Pfizer.

He replaced Dr David Dr Sparling, who in turn had taken over from bioman-about-town Dr Paul MacLeman in February 2018.

A board revamp in late 2022 saw the departure of chair Alan Fisher and directors Hugh Burrill, Mary Sontrop and Acrux CEO Michael Kotsanis.

The current chair is Mark Simari, the founder of the listed Paragon Care and chair of the listed Careteq and Tali Digital.

Rising to the challenge

Mr McDonald says his first task as CEO was to increase throughput at the Boronia plant, which was running well below capacity.

Low volumes meant the facility only had one function on the go at any one time. Now, the facility can run three to four activities concurrently.

“Volumes have increased,” he says. “Some clients left early in the stage but we convinced them to come back. We are also adding new clients.”

The Covid vaccine disappointment had a silver lining, in that IDT was awarded a \$13.9 million Federal grant. These funds were used to replace, or requalify, every piece of equipment in the sterile operation.

“For example, we didn’t have formulation capability or parenteral level inspection,” Mr McDonald says. “It’s not easy to get a TGA licence in sterile manufacturing and we now have that.”

Truly unique

The Boronia’s facility is the only ‘vertically integrated’ aseptic plant in Australia, which means it can synthesise active pharmaceutical ingredients (APIs) at scale.

A ‘sterile’ facility must meet strict standards on access, air quality and such. ‘Aseptic’ goes a step further and requires totally sterile vials, stoppers and other equipment.

“There are other facilities that do aseptic fill-and-finish, but we are the only company that can synthesise a novel API in the laboratory from design and scale it up to a [good manufacturing practice] facility,” Mr McDonald says.

“We can then convert that into a finished product, being a sterile injectable, a tablet or capsule.”

IDT’s refreshed strategy involves the developing and production of novel mRNA and antibody drug conjugate therapies. Mr McDonald says there’s no shortage of funding for mRNA work from governments, start-ups and big pharma.

“That has proved to be really successful and we are starting to grow our pipeline,” he says.

The ABC of ADCs

In essence, antibody drug conjugates (ADCs) are about replacing traditional chemotherapy with 'smart chemo'.

An ADC is made up of an antibody, with a 'linker' to a highly toxic and potent compound.

The antibody binds to the tumor receptor and the potent compound does its job.

Tapping its long experience handling cytotoxic drugs, IDT has started a pilot facility to make ADCs at small scale.

Broker Morgan Stanley estimates a current global spend of around \$US30 billion on ADCs, but this is likely to soar to \$US140 billion as they become standard for first and second-line regimens (as opposed to last-resort therapy).

While most ADCs pertain to breast cancer, Morgan Stanley sees applications in hard-to-treat cancers including lung, colorectal, pancreatic and glioblastoma.

Mr McDonald says the early ADC adopters are likely to run out of manufacturing capacity, with IDT poised to provide spillover capacity.

While IDT cannot make the actual antibody, it can synthesise the 'linkers' and the payload and fill-and-finish the final product as an injectable.

"We have a few different shots at goal," he says. "We think they will all produce revenues at different times and at different values."

Pass the pot

IDT is well placed in the medical cannabis sector because suppliers are gravitating to quality manufacturers.

The company has the capacity to extract the oils from the cannabis flowers and reformulate and bottle material in various strengths.

The TGA has helped the cause with tighter regulations, effective from July 1 this year, requiring pot preparers to comply with the same quality standards that cover other drugs.

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

The company can cater for the export market, because its TGA approved status means it is also certified in Europe, Canada and New Zealand.

And the psychedelics ...

Psychedelics are also having their day in the purple-hazed sun, as potential treatments for mental health conditions.

Advocates of these controversial therapies were heartened by the TGA's decision In February to allow the use of MDMA (3,4-Methylene-dioxy-meth-amphetamine) and psilocybin for strictly controlled research purposes, for post-traumatic stress disorder (PTSD) and treatment-resistant depression respectively.

IDT is already preparing the psilocybin ('magic mushroom') and MDMA ('ecstasy') medications for clinical trials, including the private Woke Pharmaceuticals' PTSD trial.

While the standard practice is to synthesis psilocybin rather than forage for the mushies in the field, ITD is also looking to offer a natural botanic version. The reason is that, as with cannabis, the natural stuff could contain extra beneficial compounds.

Mr McDonald says IDT has the capacity to move to commercial-scale psychedelics manufacturing "quite soon".

Finances and performance

While IDT is not obliged to issue quarterly reports, in an informal update, management disclosed June quarter revenue of \$2.4 million, 12 percent higher than the March 2023 quarter and 200 percent better year-on-year.

Revenue has grown over four consecutive quarters.

June quarter revenues were bolstered by the oral medical cannabis business and emerging psychedelics demand for research purposes.

The company also cites 60 early-stage leads, compared with 18 in the March quarter.

"We have only just entered the new financial year and the large number of proposals issued and potential leads ... put us in a strong position to deliver significant growth in revenue in 2023-'24," Mr McDonald chimes.

In early June, the company went the well to raise \$5 million in a two-tranche placement at 6.5 cents apiece, a 24 percent discount to the 15-day volume weighted average price. The company then raised \$2 million in an oversubscribed share purchase plan.

As the second tranche exceeded the 15 percent placement limit, shareholders needed to approve the measure at an EGM. They did so last Wednesday, albeit with a 30 percent protest vote.

Over the last 12 months, IDT shares have prevaricated between six cents (July 7 this year) and 15 cents (mid-August last year). The shares peaked at an all-time high of \$4.74 in June 2001.

Perennially cheap

Many biotechs claim to be valued at ridiculously derisory levels, but in the case of IDT the hard numbers justify the 'woefully undervalued' pleas.

That's because IDT's market capitalisation of \$22 million is below its circa \$8 million to \$10 million cash - that's our guesstimate in the absence of a June quarter 4C - and the \$14.55 million official book value of the Boronia property, plant and equipment.

In reality, the facility is likely to be valued at much more if it were repurposed for housing or industrial uses. Mr McDonald puts the replacement cost of the facility at north of \$100 million.

All very odd, but this discrepancy between IDT's market value and its net tangible assets has been evident for some years.

Dr Boreham's diagnosis:

Mr McDonald says management's numero uno priority is to return to profitability, with breakeven (or better) targeted for the current year.

"We are getting greater traction in APIs and an uplift in medical cannabis, while psychedelics could not have come at a better time," Mr McDonald says.

"We are then working deeper in the oncology space to bring in the advanced technology ... which will drive growth over the next two to three years."

When your columnist last looked at IDT in September 2021 - we opined that IDT has been around since the Pyramids - or so it seemed. But unlike IDT's quality-controlled output, consistency in performance has been lacking.

"Now it is about rebuilding and repositioning the company and taking it in a slightly different direction," Mr McDonald says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. * Don't be embarrassed: we had to look up 'parenteral' as well and it means drug delivery other than by mouth and has nothing to do with being a mum or a dad, with or without direction.