



Biotech Daily

Friday September 10, 2021

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market climbed 0.5 percent on Friday September 10, 2021, with the ASX200 up 37.1 points to 7,406.6 points.

Twenty-one of the Biotech Daily Top 40 stocks were up, 12 fell, six traded unchanged and one was untraded. All three Big Caps were down.

LBT was the best, up one cent or eight percent to 13.5 cents, with 1.8 million shares traded. Prescient climbed 7.1 percent; Resonance rose five percent; Compumedics, Immutep, Imugene, Opthea and Uscom were up three percent or more; Kazia, Oncosil, Orthocell, Pro Medicus, Starpharma and Volpara rose more than two percent; Clinuvel, Cyclopharm and Nova Eye were up more than one percent; with Avita, Cynata, Medical Developments and Nanosonics up by less than one percent.

Osprey led the falls, down 0.1 cents or 8.3 percent to 1.1 cents, with 224,827 shares traded. Polynovo fell 5.7 percent; Dimerix lost 4.8 percent; Actinogen and Optiscan shed more than two percent; CSL, Cochlear, Next Science, Paradigm, Proteomics and Universal Biosensors were down one percent or more; with Genetic Signatures, Mesoblast, Resmed and Telix down by less than one percent.

[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.

[RHINOMED, VICTORIA GOVERNMENT](#)

Rhinomed says the Victorian Department of Health has ordered one million Rhinoswabs for severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2) testing.

Last month, Rhinomed said that New South Wales Health Pathology had ordered one million Rhinoswabs for Sars-Cov-2 testing (BD: Aug 11, 2021).

Today, the company said that Rhinoswab was “more comfortable and easier to use than the standard nasal swab” and accelerated the sample collection process.

Rhinomed said it was continuing to scale up its manufacturing capabilities “to accommodate growing domestic and international demand”.

Rhinomed chief executive officer Michael Johnson said the company was “pleased to receive further validation of the Rhinoswab from the Victorian Government”.

“The Rhinoswab can make a meaningful impact on the Sars-Cov-2 testing process and enable more people to be tested quickly and easily,” Mr Johnson said.

“With well over two billion Sars-Cov-2 tests having been carried out globally over the last 18 months ... there is a major opportunity for Rhinoswab to radically improve testing process, clinical outcomes and user experience,” Mr Johnson said.

Rhinomed said that the Rhinoswab was US Food and Drug Administration and Australian Therapeutic Goods Administration registered and had Conformité Européenne (CE) mark. The company said it had appointed Antimicrobial Technologies as a distributor in Western Australia, Biotrading Benelux BV for Belgium, the Netherlands and Luxembourg.

Rhinomed was unchanged at 37.5 cents with 9.2 million shares traded.

[QRX PHARMA](#)

QRX says it is reviewing its structure to continue as a viable company in the medical industry and hopes to re-list on the ASX.

On May 25, 2007, QRX said it had raised \$50 million to list on the ASX to develop its dual opioid combination drug for pain, with directors including Resmed founder Dr Peter Farrell, Dr John Holaday, Gary Pace, Michael Quinn and Peter Campbell.

In 2018, the ASX delisted QRX, which followed the company’s failure to secure US Food and Drug Administration approval for its Moxduo combination of morphine and oxycodone for pain, and a subsequent period of voluntary administration (BD: May 23, 2018).

In a September 7, 2021 letter to shareholders, QRX said it had completed its 2019, 2020, and 2021 financial accounts and intended to hold an annual general meeting “in the coming weeks”.

“During this restructure the company will put to shareholders an opportunity to invest into the re-structure ... [and would] remain in the medical industry ... appoint new directors ... and will have an exciting future”.

QRX said it had “been through a traumatic time”, a class action had been completed and departing shareholders were paid earlier this year.

The company said its directors had acted in a caretaking capacity while the class action was completed and reviewed opportunities.

The QRX website said that it was “an unlisted Australian company seeking new opportunities for relisting” and its three non-executive directors were lawyers Anthony Jefferies, Matthew Worner and Lee Christensen.

The website said that a deed of company arrangement effectuated on December 23, 2015 returning the management and control to the board with “all historic liabilities ... accounted for” and the focus was identifying the opportunities to assist reinstatement to the ASX.

On October 5, 2019, Dr John Holaday died from a stray gunshot wound inflicted as he was on his way to a business meeting in Charlotte, North Carolina (BD: Oct 9, 2019).

CORRECTION: EPSILON HEALTHCARE

Last night's edition contained an incorrect closing price and trading volume for Epsilon. Epsilon was up 1.5 cents or 10 percent to 16.5 cents with 1.9 million shares traded. The medical marijuana sub-editor has been relieved of their duties and will spend a period of time reassessing their career at Weed, Need, Feed & Seed. Epsilon fell two cents or 12.1 percent to 14.5 cents with 1.9 million shares traded.

NEUREN PHARMACEUTICALS

Neuren Pharmaceuticals has requested a trading halt "pending the release of an announcement ... regarding a proposed capital raising". Trading will resume on September 14, 2021, or on an earlier announcement. Neuren last traded at \$2.25.

TOTAL BRAIN

Sun Hung Kai Group says it has increased and been diluted in Total Brain from 50,625,000 shares (7.27%) to a consolidated 6,992,500 shares (5.24%). The Cayman Islands, Virgin Islands and Hong Kong-based Sun Hung Kai Group did not disclose the number or cost of shares acquired, as required under the Corporations Act 2001. Sun Hung Kai director Brendan James McGraw said that between May 1, 2019 and August 19, 2021 the Group's shares were diluted due to share issue and were subject to the company's 10-to-one consolidation on January 24, 2020. In July, Total Brain announced a \$6.5 million capital raising at 26 cents a share, comprising a \$2.5 million placement and a \$4 million rights offer (BD: Jul 21, 2021). Total Brain was up half a cent or 2.1 percent to 24 cents.

POLYNOVO

Polynovo says that Dr Anthony Kaye has resigned as chief operating officer, effective from October 5, 2021. Polynovo said Dr Kaye joined the company from CSL and was returning to CSL "in a more senior position". The company said it was conducting a search for a replacement chief operating officer. Polynovo fell 11 cents or 5.7 percent to \$1.915 with 7.2 million shares traded.

OVENTUS MEDICAL

Oventus says it has appointed Michael Fisk as its California-based head of finance. Oventus said Mr Sisk had more than 25 years' experience in finance and accounting, most recently Signature Analytics finance executive at, where he provided support to a number of medical technology businesses. The company said Mr Sisk would "build a strong finance hub to support the increasing needs of Oventus' North American operations". Oventus was unchanged at 11.5 cents.