Biotech Daily

Friday August 11, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ATOMO UP 11%; PATRYS DOWN 10%**

*** DR BOREHAM'S CRUCIBLE: IDT AUSTRALIA**

*** AVITA H1 REVENUE UP 41% TO $34m; LOSS UP 25% TO $30m**

*** RESPIRI RAISES FURTHER $900k; TOTAL $3.9m**

*** TELIX DOSES 1ST CHINA ILLUCIX PATIENT**

*** IMAGION, PRESTIGE COLLABORATE ON PANCREATIC CANCER TEST**

*** M&G PLC BELOW 5% IN MESOBLAST**

*** M-D DR JOHN FRIEND REPLACES KAZIA CHAIR IAIN ROSS**

MARKET REPORT

The Australian stock market fell 0.24 percent on Friday August 11, 2023, with the ASX200 down 17.3 points to 7,340.1 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and two were untraded.

Atomo was the best, up 0.3 cents or 10.7 percent to 3.1 cents, with 1.5 million shares traded; followed by Volpara up 10.1 percent to 81.5 cents, with 327,190 shares traded.

Clinuvel climbed 9.5 percent; Pharmaxis was up 8.7 percent; Genetic Signatures rose 5.6 percent; 4D Medical, Amplia and Avita improved more than four percent; Orthocell and Polynovo were up more than three percent; Impedimed and Medical Developments rose more than two percent; Nanosonics was up 1.8 percent; with CSL and Resmed up by less than one percent.

Patrys led the falls, down 0.1 cents or 10 percent to 0.9 cents, with 110,651 shares traded.

Starpharma fell 9.1 percent; Universal Biosensors lost 6.45 percent; Dimerix and Micro-X fell more than four percent; Immutep was down 3.3 percent; Actinogen, Mesoblast and SDI shed more than two percent; Imugene Neuren, Prescient, Pro Medicus and Proteomics were down more than one percent; with Cochlear, Next Science, Paradigm and Telix down by less than one percent.

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 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 bio man-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.

“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 psylocibin ('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.

AVITA MEDICAL

Avita says revenue for the six months to June 30, 2023 was up 40.5 percent to $US22,303,000 ($A34,182,814) with net loss up 24.7 percent to $US19,604,000 ($A30,045,000).

Avita said commercial revenue from sales of its Recell system for the treatment of burns was up $US22.3 million for the six months to June 30, with other revenue primarily from the US Biomedical Advanced Research and Development Authority (BARDA) contract down 9.96 percent to $US1,157,000.

The company said that expenses relating to sales and marketing, general and administrative and research and development were up 36.3 percent to $US40,665,000.

Avita said expenses included the “increase of the commercial organization in preparation of its full-thickness skin defect launch” and about $2.0 million of expenses in research and development of the Recell Go device.

Avita chief executive officer Jim Corbett said the company “had an extraordinary second quarter with significant revenue growth, two landmark [US Food and Drug Administration] FDA approvals, and a pivotal FDA submission”.

“Collectively, these approvals and submission mark significant advancement of our platform, empowering us to continue to unlock our global potential,” Mr Corbett said.

Avita said diluted loss per US share was up 23.8 percent to 78 US cents, net tangible asset backing per share was down 26.9 percent to $US2.6631 and it had cash of $US37,485,000 at June 30, 2023 compared to $US34,737,000 at June 30, 2022.

Avita was up 25 cents or 4.6 percent to $5.72 with 559,260 shares traded.

RESPIRI

Respiri says it has raised $900,000 in a private placement at 3.4 cents a share, taking the total raised to $3.9 million.

Earlier this week, Respiri said its share plan had raised $2,385,420 and the shortfall raised $614,580, for a total of $3,000,000 at 3.4 cents a share (BD: Aug 8, 2023).

Today, the company said that investor would receive one option for every two shares bought, exercisable at 6.5 cents each by June 30, 2025.

Respiri fell 0.8 cents or 19.05 percent to 3.4 cents with 4.4 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has dosed the first of up-to 110 patients in its phase III registration study of Illuccix for imaging prostate cancer using positron emission tomography in China.

Last year, Telix said China’s National Medical Products Administration had approved its TLX591-CDx Illuccix kit for prostate cancer imaging study (BD: Oct 17, 2022).

Today, the company said the phase III study was a prospective, open-label, single-arm, multi-centre study in Chinese patients with biochemically recurrent prostate cancer that was “intended to bridge to the marketing authorization granted to Illucix by the US Food and Drug Administration” (BD: Jan 16, 2022).

Telix said the study was a collaboration with its China partner Grand Pharmaceutical Group and was required to establish that the diagnostic utility of Illucix was equivalent in Chinese and Western populations.

Telix Asia Pacific regional medical director Dr Shams Arifeen said the trial brought advanced prostate-specific membrane antigen with positron emission tomography (PSMA-PET) imaging “one step closer for Chinese men with prostate cancer”.

Telix fell nine cents or 0.9 percent to $10.02 with 1.4 million shares traded.

IMAGION BIOSYSTEMS

Imagion says it has an agreement with the San Diego-based Prestige Biopharma for a non-invasive, early detection pancreatic cancer diagnosis and staging platform.
Imagion said the memorandum of understanding allowed it to use Prestige's target protein silencing pancreatic adeno-carcinoma upregulated factor (PAUF) as a biomarker with its molecular magnetic resonance imaging (MRI) platform.
The company said PAUF was overexpressed in more than 80 percent of pancreatic cancer patients and that combining its Magsense MRI and Prestige's PAUF-based antibody drug PBP1510 aimed to accelerate accurate diagnosis and intervention.
Imagion did not specify the commercial terms of the agreement.
The company said the agreement covered "pre-clinical feasibility research that should be completed in a matter of months [and] should the research produce favorable results, both companies would expand the collaboration to further advance the technologies".
Imagion said that each company would bear its own costs during the period of the memorandum with expenses during this phase "well within the scope of normal pre-clinical feasibility [research and development] initiatives.
Imagion chief executive officer Dr Isaac Bright said it was an "important opportunity to deploy our Magsense molecular MRI platform technology for improved detection and diagnosis of solid tumors and metastatic disease".
"Prestige Biopharma is an innovative collaborator with whom we intend to accelerate access to, and improve management options for, pancreatic cancer patients and their healthcare providers," Dr Bright said.
Imagion was up 0.2 cents or 14.3 percent to 1.6 cents with 31.0 million shares traded.

MESOBLAST

M&G Plc says it has ceased its substantial shareholding in Mesoblast.
Yesterday, the London-based M&G Plc said it reduced its holding in Mesoblast from 58,312,858 shares (7.16%) to 48,079,421 shares (5.91%) (BD: Aug 10, 2023).
Today, M&G Plc said it sold 22,008,336 shares in 12 separate transactions, with the single largest trade 12,203,554 shares on August 9 for $4,149,208, or 34 cents a share.
Mesoblast fell one cent or 2.7 percent to 36 cents with 17.6 million shares traded.

KAZIA THERAPEUTICS

Kazia says managing director Dr John Friend will replace chair Iain Ross as interim chair, effective from today.
Dr Friend said Mr Ross was appointed chair in 2017 and had "provided the team with invaluable insights that have helped position the company for long-term success."
"As a late-stage oncology company, we will continue to assess and evaluate the mix of skills and experience that would be most beneficial to the board as we advance the development of our product candidates," Dr Friend said.
Kazia was unchanged at 14 cents.