Biotech Daily

Friday August 3, 2018

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: AIRXPANDERS UP 31%; MEDICAL DEV DOWN 9%**

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

*** RESMED REVENUE UP 13% TO $3b, PROFIT DOWN 8% TO $429m**

*** TELIX ELIGIBLE FOR $55m OFF-SHORE SPENDING TAX REBATES**

*** AIRXPANDERS PLACEMENT, RIGHTS OFFER FOR $20.3m**

*** TPI: $9m CODEINE DEAL**

*** ALLEGRA WINS $2.4m FOR KANGAROO LIGAMENTS**

*** PHARMAXIS REQUESTS PLACEMENT TRADING HALT**

*** GENETIC SIGNATURES NAMES AUSTRALIAN CLINICAL LABS**

*** VOLPARA: 900k IN-THE-MONEY DIRECTORS OPTIONS AGM**

*** MACH7: PROF SIEGEL, DAVID CHAMBERS IN; DR FINCH, NOBUHIKO ITO GO**

MARKET REPORT

The Australian stock market fell 0.1 percent on Friday August 3, 2018 with the ASX200 down 6.1 points to 6,234.8 points. Eighteen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and three were untraded. All three Big Caps were up.

Airxpanders was the best, up 3.1 cents or 31.3 percent to 13 cents with 8.3 million shares traded.

Genetic Signatures climbed 23.4 percent; Impedimed rose 11.8 percent; Prescient was up 9.1 percent; Compumedics and Telix were up more than five percent; Reva was up 3.85 percent; Benitec, Immutep and Nanosonics rose more than two percent; CSL, Optiscan, Orthocell, Polynovo and Pro Medicus were up one percent or more; with Cochlear, Cynata, Mesoblast, Resmed, Sirtex and Volpara up less than one percent.

Medical Developments led the falls, down 42 cents or 9.4 percent to $4.04, with 313,650 shares traded. Factor Therapeutics fell 7.3 percent; LBT lost 3.85 percent; ITL, Oncosil and Starpharma shed more than two percent; with Actinogen, Avita, Bionomics, Opthea and Universal Biosensors down more than one percent.

DR BOREHAM'S CRUCIBLE: IDT AUSTRALIA

By TIM BOREHAM

ASX code: IDT

Share price: 7.8 cents; **Shares on issue:** 245,157,438; **Market cap:** $19.1 million

Chief executive officer: Dr David Sparling

Board: Alan Fisher (chairman), Hugh Burrill, Mary Sontrop, and Graeme Kaufman

Graeme Kaufman was executive chair but resigned from in November 2017. Former CEO Dr Paul MacLeman resigned in July 2017 with Reo Shigeno departing in March 2018

Financials (December half): revenue $5.0 million (up 2%), operating loss $3.1 million (previously $2.8 million loss), net loss $17.2 million ***** (previously $11.7 million profit ******), cash $8.8 million (up 5%).

***** Reflects $14.14 million impairment of intangible assets relating to generics portfolio.
****** Reflects $14.5m gain on sale of the CMax business

Major identifiable holders: Regal Funds Management 10%, Sandon Capital 6.6%, l'Rom Group 6.4%, CVC (Alexander 'Sandy' Beard) 6.25%, IDT founder Graeme Blackman 2.8%, Belgravia Strategic Equities (Geoff Lord) 1.8%.

The shares in what's one of Australia's oldest listed life sciences companies are going for a song, as investors hope IDT can sing a different tune after its recent follies.

IDT's sub-$20 million market valuation compares with a cash balance of more than $8 million and the circa $19 million of its property plant and equipment (the company's state-of-the-art facility at Boronia in outer eastern Melbourne).

The value disconnect has not gone unnoticed, with activist investors Sandon Capital and CVC recently joining the register.

A frank review by directors Graeme Kaufman and Mary Sontrop in February outlined "a cumbersome organizational structure, poor operational execution, manufacturing and operational inefficiencies and under-utilized facilities [at the Boronia plant]".

But the company is fighting back under a new strategy that has included divesting most of its generics business.

Strategy U-turn

IDT specializes in high potency and difficult to manufacture drugs, all made at its Boronia plant. From initial drug development to clinical trials, IDT is the partner of choice for pharma giants including Pfizer, Johnson & Johnson, Roche, Teva and Bayer.

In 2014, IDT entered the US generics game, paying $US18 million for the package of 23 drugs. At the time, the company touted the deal as a way to increase utilization of the largely fixed-price Boronia asset and expand margins by both manufacturing and selling the products.

The trouble is a rash of new US generics filings greatly increased competition, so that the company was vying with a dozen rivals rather than three or four.

At the same time, the wholesale sector consolidated, which meant IDT was dealing with far fewer buyers.

In April this year, IDT waved the white flag, selling the drug portfolio – except for temozolomide - to ANI Pharmaceuticals for $US2.73 million, plus an ongoing profit share on one drug.

According to the February review, the company saw generics pricing erosion of between five percent and 60 percent and “the price deterioration continues”. Margins for generics are nowhere near as flash as the original branded product.

Tellingly, of the 23 generics acquired only one was launched and a further three were deemed commercially viable.

IDT’s key remaining generic is temozolomide, an oral brain cancer drug distributed by Mayne Pharma.

Potted history

While your columnist was snug in his mother’s womb in 1965, IDT was conceived 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.

Dr Blackburn resigned from the board in June last year. Another long-serving director, ex Elders board member Geoff Lord pulled stumps in mid-2016.
Thankfully for attendees at the company’s AGMs, the duo’s departures spare the Australian Shareholders Association from having to bang on about the need for board renewal.

With former chief executive officer Dr Paul MacLeman departing in July 2017, the board in February appointed vice prez for business development Dr David Sparling as interim chief executive officer and then anointed him permanently to the role in early July.

The board also appointed two ex big pharma heavy hitters as new veeps: Jim Sosic to oversee operations and Gordon Brien to take care of quality.

Not a love letter

Alas, the Victorian Manufacturing Hall of Fame gong bestowed on IDT in May last year was consigned to the staff pool room after parcel service UPS delivered a plain brown envelope from the FDA in late May, this year.

An FDA warning letter, the epistle outlined quality breaches at the Boronia plant detected during a regular audit in December last year.

The FDA noted “out of specification results and deviations”, a lack of timely corrective actions and “the ability of IDT’s quality systems to ensure integrity of data to support manufacturing of its products”.

On June 6, 2018, the company reported remediation was well underway, including the appointment of a consultant, Seerpharma’s Andrew Giles, who is well-versed in such matters.

IDT also noted there was nothing in the FDA letter precluding the company from exporting its drugs to the US.

“It was a real shock and a blow,” Dr Sparling says. “We will rise to the task and will address the FDA’s concerns. We are working through the process with the FDA now.”

The road to redemption

The February strategic review outlined four options, ranging from a partial generics exit to winding up the company.

As the April sale attests, the board opted to stick with the generics that play on IDT’s experience with cytotoxic drug making (such as the chemotherapy drug thiotepa, a derivative of mustard gas).

Otherwise, IDT plans to beef up its contract manufacturing of both finished drugs and approved pharmaceutical ingredients (APIs).

“The Boronia facility is unique,” Dr Sparling says. “Other entities in the Australian market do some of the things but certainly not all of them.”
Dr Sparling says utilization at Boronia is improving, to around 30 to 50 percent, depending on the manufacturing line.

“We have 10 buildings and different manufacturing pods within these buildings. Some will run north of 70 percent capacity and some will be lower.

“But generally speaking our utilization and execution is a lot better than what we had been doing over the previous 12 months.”

In a staged process completed in August last year, IDT sold its CMax clinical trials business to a Japanese buyer for a cumulative $16.5 million.

Financially speaking

IDT reported a $17.2 million loss for the half year to December 2017, the result of a $14.14 million impairment of the value of the generics portfolio. But even without this one-off charge, IDT incurred a $3.05 million operating loss.

But IDT's balance sheet looks a picture of health with $8.8 million cash, minimum debt and net assets of $31.85 million.

The 12,000 square metres of Boronia freehold land is in the books at a $4.38 million fair value. This is a conservative number given it was last valued in May 2016 and Melbourne's industrial values have soared since then. If rezoned to residential the land would fit an untold number of McMansions and an infinite number of apartments.

The company's property plant and equipment combined is valued at $18.91 million (as per the half-year accounts) but the replacement value is more like $50 million to $70 million.

IDT is carrying $25.8 million of tax losses - a nice asset for a buyer that could engineer a way to use them.

Dr Boreham's diagnosis:

IDT shares peaked at just under $2 in September 2008 and are just off their February 2018 record lows of around 7 cents.

But as Frank Sinatra said, "That's Life" and things look to be on the up. The company says it is meeting the industry standard of 90 percent-plus schedule adherence and on-time delivery.

In the June 6 update on the FDA's concerns, IDT also reported a strong order book up to June 30.

As for Sandon and CVC's brooding presence on the register, we understand that neither fundie has made any particular requests (or demands) of management.

IDT is not the only Aussie biotech to come a cropper in the US generics market.

Just ask generic king Mayne Pharma, which reported an impairment laden $174 million first-half loss. Or generics aspirant Acrux, which is trading at close to its cash backing.

IDT's full year results, to be released next month, should show at least some evidence of a turnaround.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort – generic or otherwise.

RESMED

Resmed says that record revenue for the 12 months to June 30, 2018 was up 13.2 percent to $US2,340,196,000 ($A3,178,337,197) with net profit after tax down 7.8 percent to $US315,588,000 ($A428,674,226).
Last year, Resmed reported record revenue but with net profit after tax down 2.9 percent to $US342,284,000 ($A429,801,850) (BD: Aug 2, 2017).
Today, Resmed said that cash at June 30, 2018 was up 12.4 percent to $US188,701,000, with diluted earnings per share down 8.75 percent to $US2.19.
The company said it would pay a dividend of 3.7 US cents a share for the three months to June 30, 2018 for shareholders on the record date of August 17, 2018, to be paid on September 20, 2018, compared to 3.5 US cents last year.
Resmed was up five cents or 0.35 percent to $14.45 with 3.3 million shares traded.

TELIX PHARMACEUTICALS

Telix says it is eligible to claim up to $55.2 million in foreign research and development expenses as Australian spending for taxation purposes.
Telix said that the Federal Department of Innovation, Industry and Science had “granted certificates” for off-shore research and development expenses on its diagnostic and therapeutic targeted radiopharmaceuticals.
The company said that the certificates, issued under section 28a and section 28c of the Industry Research and Development Act 1986 related to “highly specific works of pre-clinical, clinical, manufacturing and regulatory-related activity undertaken internationally by Telix in relation to its diagnostic and therapeutic oncology programs in kidney cancer (TLX250), prostate cancer (TLX591) and glioblastoma (TLX101)”.
Telix said that the certificates were issued to enable partial recovery of overseas research and development expenditure essential to its programs but could not be executed domestically by Australian vendors and service providers.
Telix chief executive officer Dr Christian Behrenbruch told Biotech Daily the decision made the company “eligible for 50 percent of overseas research and development spending up to $55 million to be treated as equivalent to Australian spending for tax purposes”.
Telix group chief financial officer Douglas Cubbin said the finding “reflects over a year of effort and extensive documentation evidencing the robustness and validity of our product development programs”.
“The impact of this finding is $55.2 million over five years with a likely impact of approximately $8 million to $10 million in the current financial year,” Mr Cubbin said.
“As such, this represents an important source of additional non-dilutive funding for the company,” Mr Cubbin said.
Dr Behrenbruch said the company was “grateful for the consideration given … by Innovation and Science Australia and value the financial impact this award will have on our cancer programs”.
“Along with the $50 million raised in our highly successful public offering in November last year, Telix is positioned to deliver significant clinical and financial outcomes to patients, shareholders and the Australian tax-payer,” Dr Behrenbruch said (BD: Nov 15, 2017).
Telix said that it endeavored to use Australian vendors and clinical service providers wherever possible, but “due to the advanced nature of Telix’s clinical programs, it is often necessary to conduct research, manufacturing and clinical activities in international jurisdictions, including from vendors and service provider that are authorized to perform activities under highly specialized and regulated conditions”.
Telix was up 3.5 cents or 5.6 percent to 66.5 cents.

AIRXPANDERS

Airxpanders says it aims to raise about $20.3 million through a placement and an underwritten pro-rata non-renounceable 15-for-16 rights offer.
Airxpanders said the rights offer hoped to raise $15.7 million through the issue of 208,893,798 Chess depositary interests (CDIs) at 7.5 cents each, a 22.5 percent discount to the 5-day volume-weighted average price.
The company said that chairman Barry Cheskin and the Palo Alto, California-based Vivo Ventures would buy 20,441,183 us shares at about 16.7 US cents (22.7 Australian cents) a share, to raise about $US3.4 million ($A4.6 million).
Airxpanders said that one US share was equivalent to three CDIs.
The company said the funds would primarily be used to continue the company's US commercialization efforts, as well as going towards its working capital, investment in sales and marketing, and manufacturing and product improvements.
The company said the record date was August 8, the offer would open on August 13 and close on August 22, 2018.
Airxpanders said that Cannacord Genuity (Australia) was the rights offer underwriter.
Airxpanders was up 3.1 cents or 31.3 percent to 13 cents with 8.3 million shares traded.

TPI (TASMANIAN POPPY INDUSTRIES) ENTERPRISES

TPI says it has a three-year $9 million codeine phosphate supply agreement with "one of Europe's leading pharmaceutical contract manufacturing organizations".
TIP said it would ship narcotic raw material from its plant in Melbourne to its Norwegian operations, where it would be processed into codeine phosphate active pharmaceutical ingredient and then delivered to the unnamed contractor's European formulation manufacturing site for conversion into finished dosage tablets.
The company said the agreement had a minimum supply of six tonnes each year, with $3.5 million of the expected $9 million revenue for one year's supply from August 2018.
TPI said it expected to meet or slightly exceed its half-year revenue expectations for 2018 of $20 million.
TPI was up 8.5 cents or 6.5 percent to $1.385.

ALLEGRA ORTHOPAEDICS

Allegra says it has received a $2,444,678 funding offer from the Innovative Manufacturing CRC to manufacture kangaroo-derived ligaments.
Allegra said the offer was for its collaboration with Bone Ligament Tendon Pty Ltd and the University of Sydney, to commercialize a kangaroo-derived tendon and ligament reconstruction product (BD: Aug 17, 2017).
The company said the project would develop fixation anchors and screws using manufacturing from its Sr-HT-gahnite bone substitute composed of strontium, hardystonite (a calcium-zinc-silicate) and gahnite, a zinc-aluminium-oxide (BD: Aug 25, 2017).
Allegra was untraded at nine cents.

PHARMAXIS

Pharmaxis says it has requested a trading halt, pending an announcement "in relation to the outcome of a placement".
Trading will resume on August 7, 2018, or on an earlier announcement.
Pharmaxis last traded at 31,5 cents.

GENETIC SIGNATURES

Genetic Signatures says Melbourne's Australian Clinical Labs was the unnamed pathology laboratory it said it had a contract with yesterday (BD: Aug 2, 2018).
Today, Genetic Signatures updated its announcement from yesterday in accordance with Section 4.15 of ASX Guidance Note 8.
Genetic Signatures was up 11 cents or 23.4 percent to 58 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says shareholders will vote to issue 450,000 options each to directors Dr Monica Saini and Paul Reid at the company's annual general meeting.
Volpara said the Mr Reid's options would vest in four tranches annually on March 22, from 2020 until 2023, with 40 percent in the first tranche and 20 percent each in the following three tranches, exercisable at 60 cents each by March 22, 2025.
The company said the Dr Saini's options would vest in the same manner from August 23, 2020 until 2023, exercisable at 60 cents each by August 23, 2025.
Volpara said the meeting would vote on the election of directors Roger Allen, Mr Reid, and Dr Saini, the ratification of the issue of 10,450,688 placement shares and approval of the 10 percent placement capacity.
The meeting will be held at Level 7, 44 Victoria Street, Wellington, New Zealand on August 23, 2018 at 12pm New Zealand time (10am AEST).
Volpara was up half a cent or 0.6 percent to 81.5 cents.

MACH7 TECHNOLOGIES

Mach7 says it has appointed Prof Eliot Siegel and David Chambers as non-executive directors replacing founder Dr Nigel Finch and Nobuhiko Ito, effective today.
Mach7 said that Prof Siegel was the University of Maryland School of Medicine, Department of Diagnostic Radiology, professor and vice-chair as well as the Veterans Affairs Maryland Healthcare System chief of radiology and nuclear medicine.
The company said that under Prof Siegel's guidance, the Maryland Healthcare System became the first filmless healthcare enterprise in the US.
Mach7 said that Prof Siegel had written more than 200 articles and book chapters about picture archiving and communication systems and digital imaging, as well as editing six books on the topic.
The company said that Mr Chambers had more than 30 years' experience in the healthcare and life science industry and a track record in healthcare information technology systems with executive roles in Australia, North America, Europe, and Asia.
Mach7 said that Mr Chambers was currently Allscripts Healthcare Solutions Asia-Pacific managing-director and was previously Pro Medicus chief executive officer and had worked for Agfa Healthcare, Bayer Diagnostics and Merck.
Mach7 was up five cents or 27.8 percent to 23 cents.