



Biotech Daily

Friday July 20, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: PRESCIENT UP 9.5%; OSPREY DOWN 7.5%**
- * **DR BOREHAM'S CRUCIBLE: PRANA BIOTECHNOLOGY**
- * **SIENNA RAISES \$1.6m; \$3.6m RIGHTS ISSUE**
- * **NOVITA RAISES \$2.8m; TO SELL NEWLY TO HEALTHCARELINK**
- * **COGSTATE EXPECTS REVENUE UP 9.6% TO \$39m, \$2.6m LOSS**
- * **ORTHOCELL ADDITIONAL CELGRO EURO PATENT**
- * **KAZIA FILES \$136m US SEC 'SHELF' REGISTRATION**
- * **ALCIDION ONE QUARTER CASH, 'SUBSTANTIAL' REVENUE EXPECTED**
- * **RENAISSANCE BELOW 5% IN GENETIC TECHNOLOGIES**
- * **AVITA HIRES 3 FOR US RECELL LAUNCH; PROMOTES DR KATIE BUSH**
- * **NANOSONICS JOINT CO SEC ROBERT WARING RETIRES**

MARKET REPORT

The Australian stock market was up 0.37 percent on Friday July 20, 2018 with the ASX200 up 23.2 points to 6,285.9 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and five were untraded. All three Big Caps were up.

Prescient was the best, up one cent or 9.5 percent to 11.5 cents with 229,350 shares traded. Imugene climbed 9.1 percent; Orthocell was up 8.2 percent; Compumedics rose 6.9 percent; Clinuvel improved 3.1 percent; Cochlear, Immutep and Reva rose more than two percent; Airxpanders, CSL, Mesoblast, Optiscan, Resmed, Starpharma and Telix were up more than one percent; with Nanosonics, Sirtex and Volpara up by less than one percent.

Yesterday's 33.3 percent best, Osprey, led the falls, down 1.5 cents or 7.5 percent to 18.5 cents with 455,275 shares traded. Avita lost 6.6 percent; Benitec and Factor Therapeutics fell more than five percent; Ellex and Pharmaxis were down more than three percent; Cyclopharm and Oncosil shed more than two percent; Actinogen, Impedimed, Neuren and Universal Biosensors were down more than one percent; with Cynata down 0.8 percent.

DR BOREHAM'S CRUCIBLE: PRANA BIOTECHNOLOGY

By TIM BOREHAM

ASX code: PBT

Nasdaq code: PRAN

Share price: 4.9 cents

Shares on issue: 536,975,050

Market cap: \$26.3 million

Executive chair: Geoffrey Kempler

Board: Geoffrey Kempler, Peter Marks, Brian Meltzer, Dr George Mihaly, Lawrence Gozlan, Prof Ira Shoulson

Financials (March quarter): revenue nil, cash outflows \$2.46 million, end of quarter cash \$17.6 million, estimated current quarter cash burn \$4.46 million.

Major identifiable holders: HSBC (American depository receipt holders) 72.04 percent, Geoffrey Kempler (directly and through Baywick) 3.35 percent, Jagen (Bori Liberman, associated with Lawrence Gozlan) 2.90 percent.

According to leading country and western practitioner Dr Kenneth Rogers, you gotta know when to hold them and know when to fold them.

In the case of Prana, the biotech stalwart has waved the white flag on its Alzheimer's disease efforts - but it's far from retreating from the neurology field.

Instead, Prana has turned its clinical focus to two forms of Parkinsonism with no existing treatments and orphan drug designation in the US and Europe.

To do this, Prana is zeroing-in on two proteins in the brain that occur normally, but are over-expressed in sufferers.

Prana's key weapon is Dr David Stamler, the company's recently appointed chief medical officer.

At Auspex Pharmaceuticals, Dr Stamler was responsible for the approval of Austedo, or deutetrabenazine, a treatment of chorea associated with Huntington's disease (chorea is a neurological disorder resulting in jerky movements of the shoulders, hips and face).

Auspex was acquired by Teva Pharmaceuticals in mid-2015 for a handy \$US3.5billion.

Like a pharmaceutical Pied Piper, Dr Stamler took most of his key team with him when he joined Prana in May last year.

“We have someone leading our development with real runs on the board and a strong track record,” says Prana executive chair Geoffrey Kempler.

A brief history of Prana

Mr Kempler started Prana “many years ago” with Bori Liberman, a scion of the billionaire Melbourne Liberman family.

More specifically the company was founded in 1997, based on science developed in-house and with the help of boffins from Victoria’s Mental Health Research Institute, the Florey Institute, the University of Melbourne and Massachusetts General Hospital.

Prana listed on the ASX in 2000 and a Nasdaq listing followed in 2002.

“We wanted to single-handedly cure Alzheimer’s,” Mr Kempler said.

But in early 2014 Prana shares tumbled 70 percent on news that its imaging trial for Alzheimer’s disease did not meet its primary endpoint of reducing amyloid beta plaques that are implicated in the disease.

Shortly before that the shares had jumped on news that a phase II trial for Huntington’s disease met the primary endpoint of safety and tolerability (but met only one secondary endpoint, for cognitive efficacy).

The net result was that Prana shares returned to their levels of a year previously.

These trials involved a completely different compound called PBT2.

In 2015, Prana said the US Food and Drug Administration had issued a partial clinical hold limiting dosing of PBT2 for patients with Huntington’s disease.

Last year European regulators said they wanted more pre-clinical work before allowing a phase III trial for Huntington’s disease and so that was pretty much the end of that.

Mr Kempler notes that heavyweights such as Pfizer and Eli Lilly have failed to develop Alzheimer’s drugs, with Pfizer walking away from neuroscience altogether.

“It’s been very unfortunate for the patients,” he says.

“We continue to be interested in Alzheimer’s disease but in the mean-time we have had to reinvent our strategy.”

The new Prana

The reinvention involves focusing on two forms of atypical parkinsonism: multiple system atrophy (MSA) and progressive supranuclear palsy (PSP).

While Michael J Fox and the late Mohammed Ali made Parkinson's a household name, PSA and MSA are largely unknown.

Each disorder affects about 10 million people globally including 15,000 to 20,000 Americans, which makes them an orphan disease but at the higher end of the scale.

MSA and PSP sufferers decline more rapidly relative to Parkinson's disease and both afflictions are eventually fatal.

In Dr Stamler's words, they send the patient into an "unpleasant and inexorable decline".

MSA patients have difficulty maintain their blood pressure and have bowel and bladder dysfunction, while PSP patients suffer unsteady gait, frequent falls, visual difficulties and cognitive impairment.

PBT434 on trial

In late June, Prana received ethics committee approval for a phase I trial for PBT434 to dose healthy human volunteers.

The trial, which follows the usual mouse and dog stuff, aims to establish safety and test the pharmaco-kinetics. The trial, to be carried out by Nucleus Network Australia, aims to recruit 88 adults aged between 18 and 55 years.

PBT434 is a small molecule that targets alpha-synuclein and tau, intracellular proteins implicated in both Parkinson's disease and parkinsonism.

Both proteins are good to have in a normal working brain; in fact, without them neurons can't communicate. But PBT434 was shown to reduce protein accumulation in the brains of rodents induced with the diseases.

This over-abundance is closely related to iron overload. As Lang Hancock and Gina Rinehart would attest, iron is a nice thing to have but in the case of the body that's not the case.

PBT434 helps "efflux" iron from the brain cells and returns it to where it should be.

"Like an alpha-synuclein, you can't live without iron," Dr Stamler says. "It's just that it has to be in the right place in the right concentration."

PTB434 is administered orally, but is designed to overcome the pesky blood-brain barrier that has presented so many neurological drugs from working.

Financials and performance

Prana has about \$17 million of cash, which is unusual because it hasn't raised any funds for years (but it has received R&D Tax Incentives).

"We have just been very frugal," Mr Kempler says, adding the dough should tide the company over for another year.

One Nasdaq American depositary share is worth 60 Australian Prana shares.

Prana shares in the last year have traded between 7.6 cents (December 2017) and 4.2 cents (June). They peaked at \$1.16 after the Huntington's trial news in March 2014.

Dr Boreham's diagnosis:

The company hopes that PBT434 might be developed to the extent that it can tackle Parkinson's disease as well.

Mr Kempler notes there are many therapies to treat underlying Parkinson's motor symptoms such as rigidity and tremors. But there's really nothing approved that will slow the disease.

For the time being, focusing on the orphan indications seems a sagacious strategy because there's no pending competition and the market is big enough to make money.

"Our preliminary commercial analysis is there is substantial upside if we succeed," Kempler says.

Orphan diseases also mean a faster path to approval, with Prana expecting to apply for fast-track status ... eventually.

The proteins are also being targeted by others, including the Michael J Fox Foundation, Biogen/Roche and Astra Zeneca. But that's for the 'greater' Parkinson's rather than the orphan indications.

Meanwhile, PBT2 remains on the books and has potential for partnership or licencing.

Otherwise, PBT434 presents a binary outcome in that it will either work or not work in relation to the two indications.

But given the early stage nature of the clinical work, it will be years before the company has that 'eureka' or 'oh, heck' moment.

Prana is due to present further evidence of its pre-clinical success at the International Congress of Parkinson's Disease and Movement Disorders in Hong Kong on October 5.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Sadly, he does not own any iron deposits of note.

SIENNA CANCER DIAGNOSTICS

Sienna says it has raised \$1.6 million in a placement at six cents a share to Merchant Funds and David Williams and will offer a rights issue for a further \$3.6 million.

Sienna said the placement was at an 18 percent premium to the last traded price.

The company said that the Perth-based Merchant Opportunities Fund and Mr Williams, who is the chairman of Medical Developments and Polynovo as well as the principal of Kidder Williams advisory would become substantial shareholders.

Sienna said the one-for-three rights offer would be available for shareholders on the record date of July 26, it would open on July 31 and close on August 21, 2018 and would include a facility for shareholders to apply for additional shares, with a commitment from Merchant Corporate Advisory to place any shares not taken up in the offer.

In July last year, Sienna listed on the ASX, raising 4.6 million in its initial public offer at 20 cents a share to commercialize its telomerase adjunct test for cancer (BD: Jul 31, 2017).

Today, the company said proceeds from the capital raise would be used to acquire complementary technologies to expand the company's commercialization pipeline.

Sienna said that it had appointed Merchant as the lead manager for the rights offer.

Sienna was up 1.4 cents or 27.45 percent to 6.5 cents.

NOVITA HEALTHCARE

Novita says it has raised \$2.78 million through a placement at 31 cents a share and has an agreement to sell its recently acquired subsidiary Newly to Healthcarelink.

Novita said it would sell Newly, which it bought last year for its "online market-place connecting care and support professionals with people and organisations in need" to the Sydney-based Healthcarelink, which runs an online platform for the healthcare and medical industry (BD: Jul 24, 2017).

The company said it would divest its holding in Newly to Healthcarelink in return for shares and would take a cash subscription of \$400,000 in an equity raising by Healthcarelink of up to \$1.4 million, after which it would hold 10 percent of the company.

Novita said the deal valued Newly at \$600,000 and it would appoint a director to Healthcarelink's board.

The company said Healthcarelink would pay up to \$300,000, based on a multiple of monthly sales that would be determined 12 months after completion of the transaction and payable in additional equity in Healthcarelink.

The company said its \$2.78 million placement was at a 6.06 percent discount to the last closing price and the five-day volume weighted average price and the proceeds would be used for sales and marketing and expansion of its Tali Train technology for attention deficit disorders and its Tali Detect pilot program, as well as funding the Healthcarelink capital subscription as part of its sale of Newly.

Novita was up 0.3 cents or 9.1 percent to 3.6 cents.

COGSTATE

Cogstate says it expects unaudited revenue for the year to June 30, 2018 to be up 9.6 percent to \$US29.0 million (\$A39.4m), with net loss up 90 percent to \$US1.9 million.

Cogstate said that revenue growth improved in the second half of the year.

The company said that it had cash and cash equivalents of \$US4,366,303 at June 30, 2018, a decrease of \$4,938,206 over the previous year, with an expected cash burn for the three months to September 30, 2018 of \$US8,701,635.

Cogstate fell seven cents or 8.9 percent to 71.5 cents.

ORTHOCELL

Orthocell says it has been granted a European divisional patent for its Celgro collagen medical device platform for soft tissue regeneration and repair applications.

Orthocell said the patent, titled 'Method for Producing a Collagen Membrane and Uses Thereof' provided additional intellectual property to protect the Celgro product platform until June 12, 2033.

Orthocell managing-director Paul Anderson said that Celgro had "numerous competitive advantages over existing tissue repair scaffolds, particularly in the areas of tensile strength, promotion of quality tissue repair and versatility".

"Approval comes at the perfect time, as Orthocell continues driving product adoption and sales of Celgro in the European market," Mr Anderson said.

Orthocell was up 2.5 cents or 8.2 percent to 33 cents.

KAZIA THERAPEUTICS

Kazia says it has filed a \$US100 million (\$A135.7 million) "shelf registration statement with the US Securities and Exchange Commission.

Kazia said that when approved, the registration would allow it to issue up to \$US100 million of various types of securities, including ordinary shares and/or warrants, as it required over three years.

The company said that any shares issued would trade as American depository shares which currently traded on the Nasdaq under the code KZIA.

Kazia said that shelf registrations were "customary practice as they allow companies to undergo the SEC review process before commencing any offer of securities" and a company could come to market more quickly and efficiently.

The company said it had "no immediate plans to issue securities under the registration statement, and indeed, may never issue any shares under this statement".

Kazia chief executive officer Dr James Garner said that "sound capital management is about being prepared".

"The shelf registration is a common feature of capital management programs for dual-listed companies like Kazia and is a standard industry practice," Dr Garner said.

"It provides very efficient access to US capital markets to facilitate our ongoing development and growth and allows us to be ready to respond swiftly to investor interest when we need to," Dr Graner said.

Kazia fell 2.5 cents or 5.05 percent to 47 cents.

ALCIDION

Alcidion says it had \$3,090,000 in cash at June 30, 2018, with an expected cash outflow for the three months to September 30, 2018 of \$3,800,000.

A spokesperson for Alcidion told Biotech Daily that following the MKM and Patientrack acquisition it expected the combined revenue to "increase substantially" with revenue of \$13 million for the year to June 30, 2017 as guidance (BD: Apr 24, Jul 4, 6, 2018).

The company said that in the three months to June 30, 2018 it's net operating cash burn of \$70,000 reflected "a strong uplift in receipts from customers" and it had signed new contracts in the three months to June 30, 2018.

Alcidion was up 0.2 cents or 3.8 percent to 5.5 cents.

GENETIC TECHNOLOGIES

Renaissance Technologies says it has ceased its substantial shareholding in Genetic Technologies, selling 2,835,000 shares.

On July 13, 2018, Renaissance said it had reduced its holding in Genetic Technologies to 123,751,200 shares, or 5.08 percent of the company (BD: July 13, 2018).

Today, Renaissance said that on July 18, 2018 it sold the equivalent of 2,835,000 shares as American depository receipts on the Nasdaq through GF Trading LLC, Ridge Master Trading LP, RIEF RMP LLC and RIEF Trading LLC, at prices ranging between \$US1.27 to \$US1.36.

Biotech Daily believes Renaissance retains 120,916,200 shares, or 4.965 percent of Genetic Technologies.

Genetic Technologies was unchanged at 1.3 cents with 11.9 million shares traded.

AVITA MEDICAL

Avita says it has promoted Dr Katie Bush to head of medical affairs and hired three staff to support the US launch of its Recell spray-on skin device for burns.

Avita said it had appointed Donna Shiroma as general counsel, Terry Bromley as head of commercial operations and Debbie Garner as head of marketing.

The company said Ms Shiroma had 20 years of legal and compliance experience in the pharmaceutical and medical device industries working for Ascend Therapeutics, PDL Biopharma and Johnson & Johnson.

Avita said Mr Bromley led sales and marketing for Crawford Healthcare, Emergent Biosolutions and Convatec and Bristol-Myers Squibb.

The company said Ms Garner previously was Allergan dermatology marketing director.

Avita said Dr Bush would be responsible for the development and implementation of educational programs, medical-scientific communications and company-sponsored research and clinical studies, as well overseeing its medical science liaison and medical education teams.

The company said Dr Bush held a Doctor of Philosophy from the University of Massachusetts and Worcester Polytechnic Institute.

Avita said it expected its Recell pre-market approval application to the US Food and Drug Administration to be completed by October 2018 (BD: Sep 28, 2017).

Avita fell half a cent or 6.6 percent to 7.1 cents with 3.1 million shares traded.

NANOSONICS

Nanosonics says Robert Waring has retired as joint company secretary, effective from July 19, 2018, with McGregor Grant to continue as sole company secretary.

Nanosonics was up one cent or 0.3 percent to \$3.24 with 945,353 shares traded.