Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: AMPLIA UP 14%; USCOM DOWN 10%**

*** DR BOREHAM'S CRUCIBLE: TELIX PHARMACEUTICALS**

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*** MAYNE TO LOSE CEO SCOTT RICHARDS; CEO JOB MOVES US**

MARKET REPORT

The Australian stock market edged up 0.02 percent on Friday August 19, 2022, with the ASX200 up 1.7 points to 7,114.5 points. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell and 10 traded unchanged.

Amplia was the best, up 1.5 cents or 14.3 percent to 12 cents, with 300,890 shares traded. Compumedics climbed 12 percent; Antisense was up 9.1 percent; Prescient improved 8.1 percent; Volpara was up 4.6 percent; Actinogen, Cochlear, Emvision and Kazia rose more than two percent; Cyclopharm, Imugene and Pharmaxis were up more than one percent; with Pro Medicus and Starpharma up by less than one percent.

Uscom led the falls, down 0.6 cents or 9.7 percent to 5.6 cents, with 257,142 shares traded. Nova Eye and Polynovo lost six percent or more; Paradigm, Proteomics and Telix fell more than four percent; Dimerix and Oncosil were down more than three percent; Mesoblast and Next Science shed more than two percent; Atomo, Clinuvel, CSL, Immutep, Medical Developments, Nanosonics, Orthocell and Resmed were down one percent or more; with Avita down by 0.5 percent.

DR BOREHAM'S CRUCIBLE: TELIX PHARMACEUTICALS

By TIM BOREHAM

ASX Code: TLX

Share price: $6.33; **Shares on issue:** 312,916,341; **Market cap:** $1.98 billion

Chief executive officer: Dr Christian Behrenbruch

Board: Kevin McCann (chair), Dr Behrenbruch, Dr Andreas Kluge (co-founder), Dr Mark Nelson, Oliver Buck, Jann Skinner, Tiffany Olson

Financials (six months to June 30, 2022): revenue $24.05 million (up $21.1 million), loss $70.6 million (up 111%), cash of $122.6 million

Major shareholders: Gnosis Verwaltungsgesellschaft (Dr Kluge) 7.39%, Elk River Holdings (Dr Behrenbruch) 7.2%, Grand Decade (China Grand Pharmaceuticals) 3.49%

To those unfamiliar with nuclear medicine - and we would hazard a guess that's 99.9999 percent of the population (recurring) - one isotope sounds pretty much like the other.

Cancer radiotherapy dates back more than a century and English radiotherapist Frederick Soddy 'discovered' isotopes - radioactive versions of an element - in 1913.

So, to layfolk it seems puzzling that Telix has made such a splash entering the US market with a new isotope for prostate imaging, called Illuccix.

In its early days since approval, Illuccix is selling its pants off, even though there's one established competitor in the market and another in the offing.

Improved efficacy aside, Telix chief and co-founder Dr Chris Behrenbruch says it's all about more convenient access to the invisible, short-lived rays.

While rival isotopes are produced in costly cyclotrons, Telix's can be generated at any of the 150 or so 'nuclear pharmacies' scattered across the US (including in hospitals and cancer centres).

"You make it when you need it," Dr Behrenbruch says. "[Fast food outlet] Subway is successful because it's on every street corner. We're on every corner, which is really important when you are talking about a product with a couple of hours street life."

In any event, Illuccix has captured a foot-long market share, having only been launched in the US in early May.

Telix is now eyeing broader geographies, as well as its follow-up isotope to detect renal cancer. Beyond that, Telix is developing therapeutic - as opposed to diagnostic - products and is confident of having a glioblastoma treatment to market in about three years' time.

History

Telix is developing both imaging (diagnostic) and cancer therapies on its molecularly targeted radiation (MTR) platform.

A relatively new discipline, molecularly targeted radiation allows radioactive isotopes to be delivered to biological targets expressed by the cancers. As a result, healthy cells are not irradiated in the process.

Telix was founded in November 2015 by Dr Behrenbruch and Dr Andreas Kluge.

Telix listed in November 2017 after raising $50 million at 65 cents apiece. Dr Kluge founded the Dresden-based radio-pharmaceutical outfit Therapeia, acquired by Telix for a nominal cash sum and the assumption of about $1 million of debt.

Dr Behrenbruch was also the executive director of Factor Therapeutics, which is now known as Dominion Minerals and fossicks for lime and lithium in the US. ‘Nuff said.

He was also on the board of Amplia Therapeutics.

Chief business officer Dr David Cade joined Telix in October 2019, having been chief medical officer at Cochlear. Before that, he held senior roles at targeted radiation house Sirtex Medical.

Based in Melbourne, Dr Behrenbruch has been running the US operations for several months, but hopes to revert to his normal duties after the company recently appointed a “cracking” new Americas head, Kevin Richardson.

Making it big in the USA …

Telix’s breakthrough moment came in mid-December last year when the US Food and Drug Administration (FDA) approved Illuccix for prostate cancer imaging.

Australia’s Therapeutic Goods Administration (TGA) approved the product last November, so we would like to think the FDA bigwigs took their cue from their antipodean colleagues.

Technically, Illuccix is a kit for preparing gallium-68 gozetotide - more commonly known as a PSMA-11 injection - for positron emission tomography (PET) scans.

Illuccix is indicated for prostate cancer patients suspected of having either metastasized growths or a recurrence based on elevated PSA (prostate specific antigen) levels.

In the US, Telix competes with Lantheus’s prostate imaging agent Pylarify. In March. the FDA approved Novartis’s lutetium-based imaging product, Locametz (PSMA-617).

Dr Behrenbruch estimates the US Illuccix market opportunity at $US1 billion to $US1.5 billion annually.

“There’s room for plenty of players.”

… and taking on the world

Illuccix is under regulatory review in 17 countries, notably 13 European jurisdictions and the UK.

The company has temporary authorization in Brazil and has submitted a new drug application in South Korea.

Illuccix is approved for sale in Australia and New Zealand, while assent is expected in Canada - Dr Behrenbruch's birthplace - any day.

"The aim is to get as much global coverage as we can, which is something only we are doing," Dr Behrenbruch says.

Europe is a bigger market in volume terms than the US, but not so much in value because of lower reimbursement. As a rule of thumb, whatever Telix makes in the US, the rest-of-the-world sales should add 40 to 50 percent more.

"The numbers quickly add up," he says. "There are probably 20 markets where we can do $5 million to $20 million of revenue a year."

China included …

In 2020, Telix Pharmaceuticals struck an initial 10-year deal with China Grand Pharmaceutical, by which the Hong Kong-based entity became the exclusive partner to Telix in mainland China, Hong Kong, Macau and Taiwan.

(The region used to be called 'greater China' but there are a few sensitivities around that nomenclature at the moment).

The China Grand partnership is for an initial 10-year term for any therapies, with the clock to start ticking after marketing authorization.

The 10-year deal is worth "up to" $445 million, with ongoing royalties possibly exceeding this number.

China Grand has submitted an investigational new drug application for Illuccix to China's medical regulator, the National Medical Products Administration (NMPA).

It's also lobbed an application for TLX250-CDx, Telix's imaging product for renal (kidney) cancer.

This will clear the way for local bridging studies - probably enrolling 100 patients each - to confirm the FDA-guided trials.

Annually, 115,000 Chinese men are diagnosed with prostate cancer and 75,000 people with renal cancer.

Renal cancer

The company expects TLX250-CDx to be the first imaging agent specifically intended for the non-invasive assessment of patients with clear cell renal carcinoma, the most common form of kidney cancer. TLX250-CDx is subject to a phase III registration trial.

Dr Behrenbruch describes kidney cancer imaging as a $US1 billion opportunity in the US. The global trial, called Zircon, has enrolled around 300 patients scheduled for a partial nephrectomy (that is, the kidney lump is removed by a surgical urologist).

Dr Behrenbruch says the renal imaging market is about the same size as for prostate cancer, with a similar customer base of clinicians and an “equal unmet medical need”.

In the US, 155,000 kidney cancers are found from abdominal scans targeting other conditions, with a further 55,000 kidney scans at surgical stage.

He says the renal product could be sold by Telix’s existing US Illuccix sales team.

Finances and performance

In the June (second) quarter Telix generated revenue of $22.5 million - 10 times the March quarter. Of this, $19.3 million derived from maiden Illuccix sales in the US

A key point is that the company had not yet won reimbursement, so sales should rise sharply in the current quarter.

Pylarify notches up quarterly sales of around $US100 million, and broker Taylor Collison reckons Telix is on track to snare 30 percent of the market. Management won’t hazard any forecasts until the sales pattern with full reimbursement is established.

“Certainty in the first quarter demand exceeded analysts’ estimates and certainly our expectations as well,” Dr Behrenbruch says.

As of June 30, Telix had $122 million in cash, having moved quickly to raise $175 million in a placement in January 2022, shortly after the FDA approval.

Dr Behrenbruch admits it was fortunate the company moved when it did, given the ensuing “brutal” funding conditions for the biotech sector, globally. Indeed, the $25 million share purchase plan component of the raising was cancelled, after the market soured.

Over the last 12 months Telix shares have traded between $3.55 (mid-May this year) and a record $8.67 (mid-January this year). The shares traded at a low of 43 cents in early 2018 and no one rang the bell, sadly. Last Monday, the shares dived as much as 9.5 percent after China Grand said it had sold 10 million of its Telix shares - just under half its holding - for a $56 million profit.

The line from both parties is that China Grand is still very much in love with Telix, but wanted to free some funds for its clinical programs - some of which are in collaboration with Telix.

Coming up

All up, Telix has more than 20 trials underway, mainly as academic and commercial collaborations the company does not have to fund directly.

Dr Behrenbruch says he's "most jazzed up" about a glioblastoma trial, which is entering phase II stage

Another exciting one is a collaboration with Merck, combining targeted radiation with DNA damage repair inhibitor cells.

While there's a lot bubbling in the Telix pot, investor attention now focuses on the Zircon results read-out this year. Given it's almost September, we shouldn't have to wait much longer.

Dr Boreham's diagnosis:

With Illuccix, Telix went from academic proof-of-concept to a commercially-proven product and reimbursement in the space of three short years.

Without the pandemic the pace might have been even quicker.

Dr Behrenbruch describes Illuccix as a "warm-up act, a way to build capability and relationships with neurological oncologists".

The last rock concert he recalls was the Red Hot Chili Peppers at London's Hyde Park in 2015. But he was more enamored with the warm-up act: godfather of soul James Brown.

Similarly, Illuccix makes for an impressive preliminary gig and one that recently-listed ASX rivals Clarity Pharmaceuticals and Radiopharm Theranostics could struggle to emulate.

"There are a lot of small companies appearing out of the woodwork that are trying to do what we do," Dr Behrenbruch says by way of general observation.

"But it's really hard to build a global supply chain, which has cost us $100 million to develop."

If the main act - yet to come - is even better, Telix should assume superstar status. Ultimately, the biggest prize lies in therapeutics rather than diagnostics.

"The company has a lot of momentum and is well capitalized and well and truly on the way to becoming a cash generative business," Dr Behrenbruch says.

"The next 18 to 24 months are going to be commercially critical for the company."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He vaguely recalls seeing Cold Chisel in the 1980s as a support act to the touring super-band named … er … sorry, he can't remember.

COCHLEAR

Cochlear says revenue for the year to June 30, 2022 was up 10.1 percent to $1,648,300,000 with net profit after tax down 10.7 percent to $289,100,000.
Cochlear said underlying net profit, excluding $22 million in cloud computing-related expenses, was up 18 percent to $277,600,000.
The company said it “experienced improving momentum across the year as surgeries recovered following Covid shutdowns.”
“Cochlear implants, however, continued to experience variability in performance across countries with Covid and hospital staffing shortages impacting operating theatre capacity,” Cochlear said.
The company said that operating expenses increased by 15 percent “reflecting growing investment in [research and development] and market growth activities with a material increase in cloud computing-related investment”.
The company said revenue included $935,200,000 from hearing implants, $503,900,000 from its services and upgrades and $202,000,000 from its sound processor and other acoustics.
Cochlear said that 57 percent of its business came from cochlear implants, with 31 percent from services and 12 percent from acoustics.
The company said that 48 percent of its $1.5 billion revenue came from the Americas, with 35 percent from Europe the Middle East and Africa, with 17 percent from the Asia-Pacific.
Cochlear said its final franked dividend was $1.45 per share, with the record date of September 23 and payment expected on October 17, 2022.
The company said that its diluted earnings per share fell 10.8 percent to $4.396, compared to $492.6 for the year to June 30, 2021.
Cochlear said net tangible assets per share fell one percent from $19.836 to $19.661, and it had cash and equivalents of $629.3 million compared to $609.6 million at June 30, 2021.
The company said that it expected net profit for the year 2022-’23 to be $290 million to $305 million, a five to 10 percent increase on underlying net profit for 2021-’22. Cochlear
Cochlear said it expected underlying net profit for the year to June 30, 2023 to be up five to 10 percent to $290 million to $305 million.
“We expect to deliver strong growth in sales revenue and around 18 percent underlying net profit margin before cloud computing-related expenses,” the company said.
Cochlear said that net profit was expected to be weighted to the second half, the six months to June 30, 2023.
Cochlear climbed $4.66 or 2.2 percent to $218.86 with 204,205 shares traded.

INVEX THERAPEUTICS

Invex says the US Food and Drug Administration has approved its investigational new drug application for Presendin, and will begin a 240-patient phase III trial.
The company said it had FDA approval for the ‘Evolve’ randomized, placebo-controlled, double-blind, multi-centre trial of Presendin for idiopathic intracranial hypertension.
Invex said the trial would enrol patients with newly diagnosed idiopathic intracranial hypertension to determine the efficacy and safety of Presendin versus placebo, administered once weekly for 24 weeks.
The company said the primary endpoint of the trial would be the change in intracranial pressure as measured by lumbar puncture at baseline and at 24 weeks.
Invex chair Dr Jason Loveridge said the trial had “the potential to transform the lives of thousands of … living with the significant burden of this disease”.
Invex was up nine cents or 16.1 percent to 65 cents.

ANTISENSE THERAPEUTICS

Antisense says a potential therapeutic biomarker of long Covid-19 is ‘significantly modulated’ by its ATL1102 immuno-modulatory drug candidate.

In February, Antisense said it had an agreement with Chicago’s Northwestern Medicine Neuro-Covid Clinic to assess blood disease markers to determine whether patients were amenable to treatment with its ATL1102 (BD: Feb 24, 2022).

The company said the study used blood samples collected from long Covid-19 patients with neurological symptoms including brain fog and in whom blood immune cell changes were observed, to generate data on 7,000 proteins in the blood.

Antisense said the analyzed data identified a number of proteins that were significantly modulated in the blood of long Covid-19 patients when compared to both convalescent subjects who had recovered from long Covid-19 infection and healthy subjects.

Today, the company said it would explore the clinical potential of ATL1102 for long Covid, seeking funding through grant opportunities.

Antisense director of drug discovery Dr George Tachas said the data “identified potential new avenues towards diagnoses and treatment of a disease that has negatively impacted the lives of over a hundred million people around the world”.

Antisense was up one cent or 9.1 percent to 12 cents with 11.3 million shares traded.

ANTISENSE THERAPEUTICS

Antisense has told the ASX that at the time of its request for a trading halt, four actions required carrying out for an announcement to be made.

On Monday, Antisense said that it had requested a trading halt “pending an announcement in relation to reporting outcomes of the Long Covid-19 strategic collaboration” (BD: Aug 15, 2022).

In a query on Wednesday, the ASX told Antisense: ‘Not all announcements an entity may wish to make will warrant a trading halt or voluntary suspension” and requested it clarify the conditions which gave rise to its request for a trading halt.

Today, Antisense said at the time of its request for trading halt, outstanding actions central to its ability to release the announcement included collation and verification of outcomes of the collaboration, review of the outcomes with a key opinion leader, finalization of US patent applications, and final approval of the announcement.

IMMURON

Immuron says it has “deprioritized Sars-Cov-2 research to focus on the clinical development of [its] more advanced stage therapeutic drug candidates”.

In 2020, Immuron said that a study by Melbourne’s 360 Biolabs showed that its bovine colostrum-based IMM-124E had antiviral activity against severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) when compared to a high protein milk powder placebo (BD: Jul 21, 2020).

Today, the company said that while it had devoted significant resources to interrogating IMM-124E’s mechanism of Sars-Cov-2 protection, the mechanism “remains unclear”.

Immuron said that given this, the rapid evolution of the virus, and the changing treatment landscape, there were significant challenges to conducting a trial for Sars-Cov-2 with its IMM-124E.

Immuron was up 0.4 cents or 4.3 percent to 9.8 cents.

WOKE THERAPEUTICS

Woke says it has filed a provisional patent with IP (intellectual property) Australia tin relation to its psylocibin-based drug candidates WP001 and WP002.
Woke chief executive officer Nick Woolf told Biotech Daily, that if granted, the patent, titled 'Process for improving powder flow characteristics of a crystalline compound', would protect its intellectual property to August 12, 2042.
Woke is a private company.

BTC HEALTH

LHC Capital Partners says it has reduced its substantial holding in BTC from 22,319,290 shares (7.92%) to 19,500,000 shares (6.92%).
The Sydney-based LHC said that on August 16, 2022, it sold 300,000 shares in BTC, on-market, but did not specify the consideration, as required under the Corporations Act 2001.
LHC did not detail the disposal of the other 2,519,290 shares.
BTC was up 0.2 cents or 3.2 percent to 6.4 cents.

MICROBA LIFE SCIENCES

Sydney's Perennial Value Management says it has increased its substantial holding in Microba from 37,651,376 shares (13.72%) to 40,898,790 shares (14.91%).
Perennial said that from May 17 to August 18, 2022, it bought and sold shares, with the single largest purchase on August 17 of 6,691,858 shares for $1,480,239 or 22 cents a share, and the largest sale on the same day, with the same number of shares and at the same price.
Microba fell two cents or 8.5 percent to 21.5 cents.

MAYNE PHARMA

Mayne says that chief executive officer Scott Richards will retire "following a decision by the board to relocate the CEO role to the US on a permanent basis".
Mayne said Mr Richards had spent the last five years in the US on a temporary basis, but wanted to return to Australia "for personal reasons".
The company said Mr Richards would continue in the position pending a timely and orderly transition to a US-based chief executive officer.
Mayne Pharma chair Frank Condella said "I would like to thank Scott for his leadership through the successful acquisition and sale of metrics, the challenging global Covid pandemic and navigating the competitive and complex US pharmaceutical market."
"Scott's vision to evolve our US go-to market approach to improve the sustainability of the products business has already demonstrated success in dermatology," Mr Condella said.
Mayne fell one cent or 2.7 percent to 36 cents with 5.9 million shares traded.