Biotech Daily

Friday November 13, 2020

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PATRYS UP 10.5%; AMPLIA DOWN 8%**

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

*** VICTORIA $155m FOR $550m INFECTIOUS DISEASE INSTITUTE; BURNET**

*** MACH7 $5.3m TRINITY DEAL FOR EUNITY PLATFORM**

*** PYC RIGHT OFFER RAISES $5.4m, TOTAL $40.6m, $14.2m SHORTFALL**

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*** ELIXINOL REQUESTS 'CAPITAL RAISING' TRADING HALT**

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*** ELIXINOL'S PAUL BENHAIM, RAW WITH LIFE, REDUCE TRANSFER TO 15%**

*** D&G, DAVID NEWMAN, GABRIEL ETTENSON BELOW 5% IN ELIXINOL**

*** RESPIRI 65m DIRECTOR OPTIONS, CASH BONUSES AGM**

*** HYDRIX 500k CHAIR GAVIN COOTE PERFORMANCE RIGHTS AGM**

MARKET REPORT

The Australian stock market fell 0.2 percent on Friday November 13, 2020, with the ASX200 down 13.0 points to 6,405.2 points. Eighteen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and one was untraded.

Patrys was the best, up 0.2 cents or 10.5 percent to 2.1 cents, with 5.4 million shares traded. Polynovo climbed 8.6 percent; Orthocell and Proteomics were up more than seven percent; Oncosil improved 6.25 percent; Alterity, Compumedics, Kazia, Prescient and Starpharma were up four percent or more; Optiscan was up 3.1 percent; Dimerix, Opthea and Paradigm rose two percent or more; Imugene, Mesoblast and Pharmaxis were up more than one percent; with Clinuvel and CSL up by less than one percent.

Amplia led the falls, down two cents or 7.55 percent to 24.5 cents, with 506,461 shares traded. Neuren fell 4.2 percent; Cynata, Genetic Signatures, Next Science and Uscom shed more than two percent; Avita, Medical Developments and Volpara were down more than one percent; with Cochlear, Nanosonics, Pro Medicus, Resmed and Telix down by less than one percent.

DR BOREHAM'S CRUCIBLE: TELIX PHARMACEUTICALS

By Tim BOREHAM

ASX Code: TLX

Share price: $2.60; **Market cap:** $717.2 million; **Shares on issue:** 275,842,022

Chief executive officer: Dr Christian Behrenbruch

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

Financials (September quarter 2020): receipts $823,000, cash outflows $2.18 million, cash of $25.7 million (ahead of the China deal that injected $35 million of equity)

Major shareholders: Gnosis Verwaltungsgesellschaft (Dr Kluge) 8.95%, Elk River Holdings (Dr Behrenbruch) 8.95%, Grand Decade (China Grand Pharmaceuticals) 7.59%, Fidelity International 7.28%.

In media circles, the qualifier "up to" has been a handy one for headline writers over the years.

For instance, road workers vilified as bone lazy earn "up to" a six-figure wage for brandishing a lollipop, when in fact that number is the outlier for a toiler working overtime or night shifts seven days a week.

The same caution should be applied to life science deals with big pharma that promise "up to" many hundreds of millions of milestone and royalty payments - if the device actually gets to market and blitzes sales.

On this note, Telix Pharmaceuticals headline deal with the Hong Kong China Grand Pharmaceutical is worth "up to" $445 million, with ongoing royalties possibly exceeding this number.

That's predicated on the company's key imaging and therapeutic products achieving approval and sales in greater China. But our point is the amount includes a $US25 million ($AUD35 million) non-refundable upfront prepayment and a $US25 million equity investment in Telix - with no "up to" qualifier.

In other words: 70 million bucks are definitely coming through the door.

"We are delighted to be working with such a strong partner," purrs Telix chief Dr Chris Behrenbruch. "We like the culture and the can-do attitude of the company." Dr Behrenbruch says Telix might have been seen as focused on the US and Europe at the time of its 2017 listing - and indeed it was.

But the company had already identified the potential of Asia - especially Japan which has a mature nuclear medicine industry.

‘Theranostics’

Telix dubs itself a “theranostics” company, in that it’s developing both imaging (diagnostic) and cancer therapies on its molecularly targeted radiation (MTR) platform. And putting them in the correct order of diagnostics and therapy would have led to the very catchy “diarapy” which sounds more like what little babies do.

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.

Current imaging uses the unstable gas iodine, which creates “noisy” images and is poor at detecting smaller tumors.

On the imaging side, Telix is focused on renal cancer (TLX250-CDx) and prostate cancer (TLX591-CDx and TLX599-CDx). CDx is not a compact disc containing adult material: it means “companion diagnostics”. Telix is developing therapies for these indications as well as glioblastoma, or brain cancer (TLX 101).

As an MTR play, Telix shares traits with the formerly ASX-listed Sirtex Medical, which is run by none other than CGP (having acquired 49 percent of the company for $1.9 billion in 2018).

Who is Telix?

Telix was founded in November 2015 by Dr Behrenbruch and Dr Andreas Kluge and incorporated in November 2015. In one of the biggest life science initial public offers since CSL in 1994, 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 and now non-executive director of Factor Therapeutics, which has pivoted from human wound care to veterinary imaging. He was also on the board of Amplia Therapeutics, which he co-founded, but quit in February this year to focus on Telix.

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

The deal dissected

The China deal means that China Grand Pharmaceutical becomes the exclusive partner for Telix in greater China (mainland China, Hong Kong, Macau and Taiwan).

The partnership is for an initial 10-year term for any therapies, with the clock to start ticking after marketing authorization. The imaging deal is over 15 years.

As well as the aforementioned $35 million upfront payment, Telix is eligible for up to $US69 million ($AUD100 million) of milestone payments on approval from China's medical regulator, the National Medical Products Administration (NMPA).

There's a further $US156 million in sales milestones. CGP will also chuck in up-to $US65 million of clinical costs for prostate cancer (TLX591) and renal cancer (TLX250).

The imaging side is described as a sales, marketing and distribution partnership for the renal and prostate cancer diagnostics. CGP has minimum annual purchase obligations for exclusivity to be maintained.

While Telix remains responsible for manufacturing and clinical development, CGP's task is to steer approval applications through the NMPA and Telix is heartened that the agency recently approved Sirtex's Sir-Spheres for liver cancer, with this assent based on data from foreign trials.

Having said that, Telix is willing to expand its current trials to include some Chinese patients.

Telix's PET project

While positron emission tomography (PET) screening is common in the US, Europe and Japan, in Asia the more common technique is more likely to be single photon emission computer tomography (Spect).

While China has seen huge growth in PET, it has a large incumbent Spect base.

In the case of prostate cancer, men are typically diagnosed at a late stage, while renal cancer is more likely to be picked up incidentally from abdominal imaging. Telix's agent enables a PET scan to show a more accurate picture of the biology of the recurrence; and whether repeat surgery or radiation therapy is needed.

"Millions of men will get access to our prostate cancer imaging because of our commitment to get Spect as well as PET solutions for prostate cancer," Dr Behrenbruch says.

Going nuclear on pricing

While Telix's corporate mantra is "no patient left behind", cost is a key factor.

In the case of prostate cancer, Telix competes with another lutetium-based imaging product, Novartis's PSMA-617. As well as offering claimed advantages such as a single dose rather than multiple doses. TLX519 uses only about 20 percent of the lutetium isotope, the costliest component.

"In a price sensitive market, the one thing that matters most is the isotope cost," Dr Behrenbruch says. "We can make money where our competitors struggle."

Meanwhile …

Telix is awaiting European marketing approval for its prostate cancer imaging agent, filed in April. The submission pertains to the imaging of patients with elevated prostate specific antigen (PSA) after radical prostatectomy (prostate removal) or radiation therapy.

In September, Telix followed up with an application to the US Food and Drug Administration, citing clinical data from more than 600 patients as well as peer-reviewed literature. The agent is available for special access use in the US and Europe, with 12,000 men treated last financial year.

In February, Telix received positive feedback from the FDA, which deemed the current safety and efficacy data to be sufficient. Dubbed as “men’s breast cancer” because it is so common, prostate cancer is diagnosed in 175,000 patients annually in the US alone.

Many undergo a prostatectomy and are cured. But about 70,000 of them relapse and require prostate specific antigen (PSA) blood tests. The trouble is that current diagnostic imaging scans only have enough resolution to detect a one centimetre tumor, by which time it is too late.

Meanwhile, Telix’s proposed antibody-based imaging product for renal (kidney) cancer is subject to a phase III registration trial. 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.

In August, the company started a phase I/II study in Japan. Called Zirdac-JP the study aims to recruit 40 patients as a supplement to its phase III global trial, Zircon. Zircon is designed to enroll patients scheduled for a partial nephrectomy (that is, the kidney lump is removed by a surgical urologist).

Telix also has a less-advanced glioblastoma (brain cancer) program, TLX101-CDx, which has started recruiting 22 patients for a phase I/II study.

A prostate treatment?

Dr Behrenbruch says that apart from commercializing an imaging product, the “big event” for 2020 will be the launch of a phase III trial, called Prostact, for patients with PSMA expressing castration-resistant prostate cancer (mCRPC).

Telix is due to meet the FDA on November 23 to yak about final study design for the Prostact trial, which is likely to recruit 550 to 600 patients. The company hopes the regulator will allow it to “enrich” the patient selection with use of its prostate cancer imaging, to hone in on the most suitable subjects with mCRPC.

Financials and performance

Six months ago, Telix was talking about a partnering deal to fund the estimated $70 million to $80 million cost of the prostate cancer therapy trial.

Now, the China Grand equity investment and a research and a development tax refund mean the company will go into 2021with a cash kitty of $100 million.

“The company will not have to raise additional capital in the near future,” Dr Behrenbruch says.

Telix chalked up sales of a tad over $800,000 in the September (third) quarter and revenue of $3.5 million in calendar 2019 from prostate cancer imaging kits.

The $35 million of China Grand placement shares were issued at $1.69 each !!!!million, which reflected the then market price rather than a steep discount typically seen with such deals. CGP cannot trade the shares for 12 months from the date of issue.

Management estimates the CGP relationship will cost the company $3 million to service annually.

The company last raised $45 million via a placement and share purchase plan in August 2019.

Telix models annual revenues from prostate imaging at the midpoint of $US105 million ($166 million).

The kidney market is about one quarter of the size.

Meanwhile, Telix shares have traded as low as 48 cents (March 2018) and peaked at $2.64 this week (November 11, lest we forget).

Dr Boreham’s diagnosis:

Just over four years after its genesis, Telix has done well to be on the cusp of commercializing its first diagnostic product.

Ultimately, the biggest prize lies in therapeutics rather than diagnostics. If approvals are forthcoming, there’s no reason Telix can’t become another multi-billion dollar market cap Aussie biotech champion.

While Telix remains focused on Western world markets, in Asia it’s eyeing an immature but developing nuclear medicine landscape.

“In general, the isotope supply chain is not as well established as in other regions, although we see this changing very rapidly over the next five to seven years,” Dr Behrenbruch says.

“The main opportunity lies in the volume of patients in important oncology indications with large unmet medical needs.”

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has scored “up to” 27 not-out in backyard cricket, but his batting average is more like two.

VICTORIA GOVERNMENT, BURNET INSTITUTE

The Victoria Government says it will invest $155 million to establish a $550 million Institute of Infectious Disease in the Parkville precinct to “lead the fight against future pandemics”.
The State Government said the Institute would incorporate the Burnet Institute and receive $150 million from the University of Melbourne and its partners, with the remaining capital to be sought from the Federal Government.
A spokesperson for the Burnet Institute said that the move from Commercial Road to Parkville would probably take “at least four years”.
Premier Daniel Andrews said Victoria survived the Covid-19 pandemic “by backing our scientists and researchers … [and] we’ll continue to do that and create high skilled jobs”.
The Government said it expected to begin construction in mid-2021 and once operational, it could generate up 850 jobs, while supporting up to 5,000 biomedical sector jobs.
Victoria’s Minister for Innovation Jaala Pulford said the Australian Institute for Infectious Disease would give Victoria’s medical researchers :what they need to make ground-breaking discoveries that will change lives and save lives”.
In a media release, the Victoria Government said the Institute would be “designed to deliver everything researchers need to detect, analyze, manage and treat infectious diseases”, including cross-disciplinary infectious disease modelling, laboratories, high containment facilities and healthcare worker pandemic response training.
The government said the Institute would collaborate with the Walter and Eliza Hall Institute for Medical Research, the Murdoch Children’s Research Institute, the University of Melbourne and CSL “to ensure Victoria and Australia are prepared for future challenges”.

MACH7 TECHNOLOGIES

Mach7 says it has a $5.26 million agreement with Trinity Health for the licence and associated support services of its Eunity enterprize diagnostic viewer platform.
Mach7 said the seven-year contract with the Livonia, Michigan-based Trinity, a Catholic healthcare delivery system, would allow Trinity to install the Eunity enterprize viewer in its Unified Clinical Imaging platform at its 92 hospitals in 22 US states.
The company said it expected to receive the first software licence orders by December 31, 2020, and the majority of orders by June 30, 2021.
Mach7 said it would receive fees for support and maintenance services within one year of installation, which would continue for six years, with all payments totalling $5.26 million.
Mach7 chief executive officer Mike Lampron said that the agreement was “Mach7’s first material contract award since our acquisition of Client Outlook” highlighting the investment thesis around the importance of a world-class Enterprize Viewer to an imaging strategy.
In July, Mach7 said it had completed the $40,942,776 acquisition of the Waterloo, Ontario-based Client Outlook Inc, including its Eunity platform (BD: Jul 14, 2020).
Mach7 was up 11 cents or 10.8 percent to $1.13 with 3.1 million shares traded.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

PYC says it its one-for-10 retail rights offer at 17 cents a has raised $5.4 million of a hoped-for $19.6 million, taking the total raised to $40.6 million.
Last month, PYC said it hoped to raise $55 million through a $50 million entitlement offer and a $5 million placement, and later said it had raised $35.2 million in the institutional rights offer and placement (BD: Oct 20, 22, 2020).
Today, the company said it held the right to place the $14.2 million shortfall.
PYC was up half a cent or 2.9 percent to 17.5 cents with 1.65 million shares traded.

POLYNOVO

Polynovo says it has investigation device exemption approval from the US Food and Drug Administration for a 150-patient pivotal trial of Novosorb for full thickness burns.
Polynovo said the trial of its Novosorb biodegradable temporizing matrix (BTM) at 20 US sites would begin patient recruitment following hospital approvals.
The company said the Novosorb BTM clinical program was supported by funding of $US15 million ($A20.75 million) from the US Biomedical Advanced Research and Development Authority (BARDA) (BD: Jul 14, 2020).
Polynovo managing-director Paul Brennan said the FDA approval was “a significant milestone for Polynovo”.
The company said it expected patient recruitment to begin in “early 2021 and conclude around [the] end of 2023”.
Polynovo was up 24 cents or 8.6 percent to $3.04 with 8.3 million shares traded.

MEDADVISOR

Medadvisor says it has extended its digital health secure messaging pilot platform agreement with a US partner until the end of 2021.
In July, Medadvisor says it had an agreement the Irving, Texas-based Health Management Systems for a secure digital communication product to enable healthcare organizations to communicate and better deliver messages (BD: Jul 1, 2020).
Today, a Medadvisor spokesperson told Biotech Daily that that the original pilot program was expected to run until the end of 2020 but had been extended to the end of 2021.
The company said the digital health messaging pilot program was expected to run at up-to 25 percent of the Burlington, Massachusetts-based Adheris Health network, which Medadvisor secured the funds to acquire yesterday (BD: Nov 12, 2020).
Today, the company said it would bring secure digital health programs, including the messaging pilot program, to a subset of the Adheris network, which extended to 25,000 pharmacies and could reach one in two Americans on an opt-out basis.
Medadvisor was up 2.5 cents or 6.4 percent to 41.5 cents.

ACTINOGEN MEDICAL

Actinogen says its one-for-five rights offer at 2.2 cents a share has raised $1.36 million of a hoped-for $4.9 million, talking the total raised to $7.36 million.
Last month, Actinogen said it had raised $6 million in an “over-subscribed” placement and hoped to raise $4.9 million in a rights offer (BD: Oct 15, 2020).
Today, the company said the funds would be used to fund the Xanamia phase II trial for mild cognitive impairment due to Alzheimer’s disease, which was expected to begin by July 2021.
Actinogen said it reserved the right to place the remaining 161 million shortfall shares withing three months.
Actinogen was unchanged at 2.2 cents with 13.5 million shares traded.

ELIXINOL GLOBAL

Elixinol has requested a trading halt for “the purpose of considering, planning and executing a capital raise”.
Trading will resume on November 17, 2020 or on an earlier announcement.
Elixinol last traded at 18.5 cents.

AUSCANN GROUP HOLDINGS

Auscann has requested a trading halt pending an announcement regarding “a potential material transaction”.
Trading will resume on November 17, 2020 or on an earlier announcement.
Auscann last traded at 14 cents.

PROBIOTEC

Pie Funds Management says it has increased its substantial holding in Probiotec from 4,498,523 shares (6.02%) to 5,677,383 shares (7.592%).
The Auckland, New Zealand-based Pie Funds said it bought shares between September 4 and November 11, 2020 at prices ranging from $1.72 to $2.06 a share.
Probiotec fell two cents or 0.9 percent to $2.15.

IMPEDIMED

Allan Gray Australia says it has reduced its substantial shareholding in Impedimed from 95,805,454 shares (8.92%) to 81,728,991 shares (7.60%).
Sydney’s Allan Gray said that between August 6 and October 5, 2020 it sold 14,076,463 shares for $1,299,698 or 9.2 cents a share.
Impedimed was unchanged at 9.3 cents with 4.6 million shares traded.

ALTERITY THERAPEUTICS

Credit Suisse Australia says it has become a substantial shareholder in Alterity with 68,047,174 shares or 5.02 percent of the company.
The Sydney-based Credit Suisse said that it bought, sold, borrowed and returned shares between July 13 and November 11, 2020 with the single largest purchase 15,000,000 shares for $375,000 or 2.5 cents a share on November 11, 2020.
Alterity was up 0.1 cents or four percent to 2.6 cents with 4.5 million shares traded.

ELIXINOL GLOBAL

Elixinol co-founder Paul Benhaim and Raw with Life say they have reduced their substantial holding from 54,623,008 shares (28.33%) to 26,523,008 shares (15.31%).
The Mullumbimby, New South Wales-based Mr Benhaim said that between June 17 and November 12, 2020 he sold 12,100,000 shares for $1,960,000 or 16.2 cents a share and transferred 17,000,000 shares as a “loan security”.

ELIXINOL GLOBAL

D&G Health, David Newman and Gabriel David Ettenson say they ceased their substantial holding in Elixinol.
The New York and Boulder, Colorado-based D&G, Mr Newman and Mr Ettenson said they previously held 11,826,243 shares, or 6.133 percent of the company and had retained 9,474,170 shares, or 4.913 percent of the company.
D&G, Mr Newman and Mr Ettenson said that on November 10, 2020 they sold 2,352,073 shares for an average of 18.5 cents a share

RESPIRI

Respiri says it proposes to issue 65,000,000 options and cash bonuses to chair Nicholas Smedley, managing-director Marjan Mikel and director Dr Thomas Duthy.

Respiri said its annual general meeting proposed to issue 30,000,000 options to Mr Smedley, 30,000,000 options to Mr Mikel and 5,000,000 options to Mr Duthy as part of their remuneration packages, vesting immediately and exercisable at 30 cents each, within in five years.

The company said it proposed to issue a cash bonus incentive of $2,000,000 each to Mr Smedley and Mr Mikel and a $333,333 cash bonus incentive to Mr Duthy which they would receive “in the event that a qualifying exit event occurs before January 1, 2026”, with the qualifying exit event defined as any one of four events that value the company at more than $350,000,000.

Respiri said shareholders would vote to ratify the prior issue of 617,284 shares to brand ambassador and former Australian cricket captain Michael Clarke and ratify the prior issue of 181,818 shares to company secretary Alastair Beard (BD: Feb 7, 2019).

The company said shareholders would vote to adopt the remuneration report, re-elect directors Mr Smedley, Mr Mikel and Mr Duthy, ratify shares issued through a capital raising, ratify the prior issue of shares and options to its corporate advisor and consultants, approve the issue of options to employees and consultants, approve the employee share option plan and approve a 10 percent placement capacity.

The virtual meeting will be held on December 16, 2020 at 2pm (AEDT) at https://us02web.zoom.us/j/89646418034?pwd=LzNIOHRnNUQyY29xRmFQOXJZQnFWQT09.

Respiri fell half a cent or 2.9 percent to 16.5 cents.

HYDRIX

Hydrix says its annual general meeting will vote to issue 500,000 free performance rights to chairman Gavin Coote.

Hydrix said the proposed performance rights to Mr Coote would vest in two equal tranches on June 30, 2021 and 2022 based on the achievement of performance curdles in relation to financial, operational, corporate governance, strategic planning and business development targets set by the board.

The company said shareholders would vote to adopt the remuneration report, re-elect director Joanne Bryant, ratify previously issued placement shares, approve the refinance facility warrant terms and approve a 10 percent placement capacity.

The virtual meeting will be held on December 11, 2020 at 2pm (AEDT) and would be available at https://web.lumiagm.com/?fromUrl=358990866.

Hydrix was up half a cent or 1.7 percent to 29.5 cents with 1.3 million shares traded.