Biotech Daily

Friday November 17, 2017

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.23 percent on Friday November 17, 2017, with the ASX200 up 13.8 points to 5,957.3 points. Ten of the Biotech Daily Top 40 stocks were up, 11 fell, 14 traded unchanged and five were untraded.

Neuren was the best for the second day in a row, up 2.5 cents or 17.9 percent to 16.5 cents with 25.3 million shares traded. Impedimed climbed 9.1 percent; Mesoblast was up 7.7 percent; LBT improved 5.7 percent; Admedus rose 4.35 percent; Pro Medicus was up 3.8 percent; Avita and Prana rose more than two percent; CSL, Orthocell and Polynovo were up more than one percent; with Resmed up 0.2 percent.

Compumedics led the falls, down two cents or 5.3 percent to 35.5 cents, with 15,910 shares traded. Acrux lost 3.2 percent; Airxpanders, Bionomics and Clinuvel shed more than two percent; Cyclopharm, Medical Developments, Nanosonics and Pharmaxis were down more than one percent; with Cochlear, Opthea and Sirtex down by less than one percent.

DR BOREHAM'S CRUCIBLE: TELIX PHARMACEUTICALS

By TIM BOREHAM

ASX Code: TLX

Market cap: $148.1 million

Share price: 75 cents; **Shares on issue**: 197,437,500 (107,360,578 in ASX escrow)

Chief executive officer: Dr Christian Behrenbruch

Board: Kevin McCann (chairman), Dr Behrenbruch, Dr Andreas Kluge (executive director, chief medical officer, co-founder), Dr Mark Nelson, Oliver Buck

Financials: Cash of $52.4 million (the company was incorporated in January 2017 and has no trading history).

Major shareholders: Dr Behrenbruch 12.5 percent (pre listing 20.5 percent), Dr Kluge 12.5 percent (20.5 percent), Fidelity International (10%), Oncidium Foundation ***** (3.6%), scientific advisory board members (2.9%), other board members (1.3%)

***** Charitable foundation issued Telix shares for nominal cash consideration at the time of the Telix incorporation.

As Australia overwhelmingly backed marriage equality on November 15, investors said 'Yes' to Telix, backed by a list of investors GetUp! would envy, including CVC, Acorn Capital and Allan Moss.

The targeted radio-pharmaceutical play has emphatically made its debut and at the end of Wednesday's session holders were sitting on a handy 18.5 percent gain, enough for as many frocks and cakes as you could want.

The much-anticipated offer, at 65 cents apiece, raised $50 million. Believe it or not, Telix is the biggest drug development (as opposed to device) IPO since CSL graced the boards in 1994 and what a stinker that (now) ASX top-10 stock turned out to be.

"It's been a long journey. We have been on the road for four months," says CEO Dr Chris Behrenbruch.

In January, Telix raised $8.5 million in a pre-initial public offer (IPO) round, bringing on holders including Moss, CVC, Alium Capital Management and Monash Investors.

(By the way, Telix chairman Kevin McCann formerly chaired Macquarie Group – then called Macquarie Bank - so there's more than one silver doughnut link with this one).

But will the cancer therapeutics (and diagnostics) developer make it to the final furlong? There are no dead certs in cancer drug development and the field has its fair share of failures.

A more targeted approach

A relatively new discipline, molecularly-targeted radiation (MTR) allows radioactive isotopes to be delivered via Telix's patented molecules in a selective way, so that they only reach the tumors in question.

In the most layperson of terms, these agents attach to biological targets expressed by the cancers and that's how the radiation can be delivered without blasting away at healthy cells as well.

Alternatively, MTR can be used as an enhanced diagnostic tool based on existing hospital imaging equipment.

A current problem with imaging is that it uses the unstable gas iodine, which creates "noisy" images and is poor at detecting smaller tumors.

Telix's lead molecule, the antibody TLX-250 relates to renal (kidney) cancer. The others are the antibody TLX-591 for prostate cancer and the small molecule TLX-101 for gliobastoma, or brain cancer.

These programs were selected on the basis of demonstrated significant clinical efficacy at trials and the ability to be viable products (for instance, they must be able to be manufactured at scale).

New biotech kid on the block

The youngest of corporate pups, Telix was founded in November 2015 by Dr Behrenbruch and Dr Andreas Kluge and incorporated in November 2015.

Dr Kluge founded the Dresden-based radiopharmaceutical outfit Therapeia, which owned the background technology to TLX-101.

Telix acquired Therapeia in October for a nominal cash sum and the assumption of about $1 million of debt.

Dr Behrenbruch is best known as author of the acerbic biotech sector critique ASX Long Tail – at least until he received one too many lawyers' letters (and at least one death threat) from irate targets and put away his quill.

But he also has experience on the 'other side' as executive director (now non-executive director) of wound-care play Factor Therapeutics.

Telix is buoyed by other MTR successes such as Bayer's Xofigo for metastatic prostate cancer and Advanced Accelerator Applications Lutathera for neuroendocrine tumors.

"These products have been widely accepted by the oncology community and are now part of the standard of care in many countries," the company says.

Progress to date

Telix's lead program TLX-250 has already been subject to phase III imaging trials and an "academic" phase II treatment trial in Europe. Telix also has a special protocol assessment from the US Food and Drug Administration to carry out a "confirmatory" phase III trial of TLX-250 for imaging.

The antibody TLX-591 is aimed at the well-known prostate cancer target prostate-specific membrane antigen, or PSMA. A phase-two imaging study was carried out in 2016.

The small molecule TLX-101 targets brain cancer. Once again, it has been confirmed as a successful imaging tool, with a small (five patient) German study also indicating "considerable therapeutic potential."

Neither TLX-591 nor TLX-101 will be developed for imaging because there are already effective tools available.

What's next?

A TLX-250 phase III trial is expected to start in late 2017 and with Christmas looming that must mean "any day now". If successful, management expects marketing approval within 24 months – and that's from October's prospectus date and not from now.

A phase II therapeutic trial for renal cancer is scheduled to start in mid-2018, followed by a prostate therapeutic study in late 2018.

TLX-101 doesn't miss out either, with a phase I/II dose-escalation study of relapsed clinical patients expected to take place at an unspecific date across three European centres.

Multiple partners

Telix has a partnership with German publicly-listed biotech Wilex AG, which developed TLX-250 before divesting it after a failed phase III trial. The key difference is that the Wilex trial was a non-radioactive antibody therapy program, which is like providing non-alcoholic beer to schoolies and expecting a drunken orgy.

"It was an incredibly ambitious program to run with a high chance of failure," Dr Behrenbruch says.

Telix also works closely with UK biopharmaceutical provider Abzena PLC, which holds patents pertaining to TLX-591.

Then there's a "collaborative agreement" with Atlab Pharma, which owns clinical data and manufacturing intellectual property over TLX-591 (the prostate cancer program).

Telix has an option to acquire this intellectual property for $US10 million in cash and/or shares by the end of calendar 2017. Or if the festive torpor proves too much, it can extend by six months by paying $US200,000.

While it believes Telix can develop TLX-591 without the data and patent rights in question, development could be delayed for six months. Dr Behrenbruch says Telix is likely to exercise the option, but pay in scrip only. After all, none of the $50 million raised was earmarked for this purpose.

Financials

Telix opines that the funds raised should be enough for it to execute the intended programs, but we all know that in biotech enough cash is never enough in the long run.

While TLX-591 is also not the lead program, management has earmarked more for that effort ($21.5 million) than the flagship renal program. We guess that as TLX-250 is more advanced, there's less work to do.

The risk factors section of a prospectus – a.k.a. the cup of truth – always makes for interesting reading.

In the case of Telix one threat is disrupted supplies of the requisite isotopes, which unsurprisingly are made under highly-regulated conditions. Because the isotopes have a half-life of less than a week, they need to be supplied on a just-in-time basis.

Once upon a time we had a quaint thing called a car manufacturing industry which operated on the same just-in-time basis. But let's hope the similarities end there.

Dr Boreham's diagnosis:

Your columnist dare not guess the success rate of an ASX-listed drug developer (that is, one that has got a drug to market and made a few beans out of it).

Five percent? One percent?

For investors, such plays are usually more profitable along the journey rather than at the destination. Having said that, who is your humble Crucible to doubt the wisdom of the numerous moneyed backers?

As for Dr Behrenbruch, the driving force behind this one: "I'm not god's gift to bioscience but I generally know what I'm doing," he says.

With such a rock star line-up of deep pockets, Telix won't be starved of funds if its trials deliver the goods.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has not received any death threats to date so must not be trying hard enough.

RHYTHM BIO

Rhythm Bio says it hopes to raise $9,000,000 in an initial public offer at 20 cents a share to list on the ASX to develop its Colostat blood test for bowel cancer.

Rhythm Bio chief executive officer Dr Trevor Lockett told Biotech Daily that the Melbourne-based company hoped to develop the blood test to be comparable or better than the current faecal immunochemical test (FIT) screening assay.

The Rhythm Bio prospectus said that Colostat was designed to be a simple blood test as well as cost effective, minimally invasive and another option for those currently unwilling to screen, using the faecal test.

The prospectus said that the test could be easily run by laboratories, with minimal training or need for new infrastructure and would be comparable to, if not better than, the current FIT tests in detecting early stage colorectal cancers.

Dr Lockett said that the prototype test was achieving more than 70 percent in sensitivity on retrospective sample testing which he expected would by improve significantly.

Dr Lockett said the funds would cover a prospective trial and the company hoped to take the completed test to European regulatory approval, followed by Australia and the US.

The prospectus said that the Colostat blood test was expected to achieve greater patient participation and compliance than faecal tests and could be used as a triage for positive results to prioritize urgency for colonoscopy follow-up.

The company said the immunoassay, biochemical test had the potential to detect colorectal cancer at all stages and would measure the presence or concentration of multiple protein biomarkers for colorectal cancer.

Rhythm Bio said that beginning in 2003, Commonwealth Scientific and Industrial Research Organisation staff identified 68 proteins reported to vary in concentration in the blood of patients with and without colorectal cancer.

The company said that assisted by funding from the National Health and Medical Research Council, the CSIRO evaluated the 68 biomarkers across five studies and reduced it to a lead panel of “just a few” biomarkers.

Rhythm Bio said that the studies found that when certain combinations of these protein biomarkers were measured in a blood sample and their concentrations weighted using an algorithm, a colorectal cancer risk score could be determined.

“It is this patented process that forms the basis for the Colostat technology,” Rhythm Bio said.

The company said the board comprised chairman Shane Tanner, with directors Dr Lockett, Lou Panaccio and David White.

Rhythm Bio said the offer would close on November 22 and the company expected to list under the ASX code RHY on December 13, 2017 with a post-listing market cap of $20,150,000.

The company said that the lead manager for the offer was Taylor Collison.

The prospectus is available at: https://www.rhythmbio.com/prospectus/.

MACH7 TECHNOLOGIES

Mach7 says Sentara Healthcare will use its Mach7’s vendor neutral archive (VNA) system for data migration for its image management initiative.

Mach7 said that the Norfolk, Virginia-based Sentara signed a deal worth $US1.8 million ($A to manage a data migration of more than 20 million imaging studies.

The company said that Sentara needed a product that could consolidate all its imaging data across four healthcare regions.

Mach7 fell half a cent or 2.6 percent to 18.5 cents.

PRO MEDICUS

Pro Medicus says it has an $18 million, seven-year contract with Yale New Haven Health for its Visage 7 radiology imaging technology.

Pro Medicus said its US subsidiary Visage Imaging signed the deal with Yale University and Yale Medicine the clinical practice of the Yale School of Medicine, the largest academic, multi-specialty practice in New England.

The company said that the contract, based on a transaction licencing model, would see its Visage 7 technology implemented across all of Yale's radiology departments.

Pro Medicus said the Visage 7 system would be implemented at five related hospitals with the first locations scheduled to go live by early 2018.

Pro Medicus chief executive officer Dr Sam Hupert said it was "another very significant contract for us".

"Yale is one of the top academic institutions in the US," Dr Hupert said. "Their decision further validates our belief that Visage 7 is uniquely positioned to cater to the needs of the most sophisticated and demanding clinical environments."

"This is another major milestone for us in terms of market acceptance and we look to build on this as a basis for continued growth in North American and other global markets," Dr Hupert said.

Pro Medicus was up 26 cents or 3.8 percent to $7.18 with 212,135 shares traded.

OPTISCAN

Optiscan says that its Viewnvivo microscope system has been installed for evaluation at the Palo Alto, California-based Stanford University in the USA.

Optiscan said its endo-microscope system would allow pre-clinical researchers to obtain microscopic cellular and sub-cellular images in animals at higher resolution than existing technologies.

The company said Stanford University was a leading research insitute, with a research budget of $US1.6 billion ($A2.1 billion) and more than 6,000 externally sponsored research projects.

Optiscan said Stanford University had selected the Viewnvivo system for evaluation after seeing it at the World Molecular Imaging Congress in Philadelphia in September, 2017.

The company said that a successful evaluation could lead to sales to the University.

Optiscan chief executive officer Archie Fraser said the company was "honored that a university of Stanford's calibre has selected our platform, particularly as they are very aware of other existing microscopic imaging technologies".

"This is a significant validation of the Viewnvivo," said Mr Fraser.

Optiscan was untraded at 10 cents.

ADALTA

Adalta says it has been granted an Australian patent covering AD-114 for fibrosis.

Adalta said the patent, entitled 'CXCR4 binding molecules', protected the technology platform and the "composition of matter" until 2036.

The company said the new class of protein therapeutics, was developed for the treatment of idiopathic pulmonary fibrosis and other fibrotic diseases.

Adalta chief executive officer Sam Cobb said the "granted patent strengthens Adalta's patent portfolio and position around AD-114, providing a firm footing for the commercialization of our lead candidate".

Adalta was up one cent or 4.3 percent to 24.5 cents.

MESOBLAST

Mesoblast has responded to an ASX 'aware' query saying its 52-week rheumatoid arthritis data announcement on November 13, 2017, was not material.
The ASX said that Mesoblast lodged the announcement at 11.54pm (AEDT) on Friday November 10 and it was released at 8.22am on Monday November 13, 2017.
The ASX said Mesoblast shares opened at $1.28, traded at an intra-day high of $1.38 and closed at $1.37, compared to a closing price of $1.235 on November 10 and asked the company if the information was material and if so, it became aware of the information.
Mesoblast said it made an announcement in the US on Friday morning US time and lodged the ASX announcement, marked "market sensitive", on Friday at 11:54pm AEDT.
Mesoblast said the announcement was "not information that a reasonable person would expect to have a material effect on the price or value of its securities as the information, which comprised the material results and conclusions from the trial, had been previously reported to the market".
The company said the 52-week data was consistent with the 12 week and 39 week data (BD: Aug 9, 2016; Feb 16, Nov 13, 2017).
Mesoblast said that previous substantial shareholder Teva Pharmaceuticals had "sold approximately half its shareholding some two weeks earlier" and investors could have considered the removal of a perceived overhang as being "material to their investment".
Mesoblast was up 9.5 cents or 7.7 percent to $1.325 with 2.3 million shares traded.

MEDLAB CLINICAL

Medlab chairman Michael Hall says he has increased his substantial holding from 10,967,778 shares (6.82%) to 15,184,445 shares (8.37%).
The Point Piper-based Mr Hall said that on August 16, 2016 he bought 1,566,667 shares for $470,000 on at 30.0 cents a share and exercised 2,650,000 options into shares at 30 cents each on November 16, 2017.
Mr Hall said the shares were held by FIT Investments for the Hallab Investment Trust and with Elizabeth Ann Jones as trustee for the Hall Jones Superannuation Fund.
Medlab was up 5.5 cents or 8.7 percent to 68.5 cents.

PRIMA BIOMED

Prima's annual general meeting as approved all resolutions including the change of name to Immutep (BD: Oct 17, 2017).
Prima said it acquired Immutep in 2014 and since the sale of its CVac ovarian cancer vaccine its focus had been on LAG-3 immunotherapies (Dec 17, 2014; May 13, 2016).
Prima chair Lucy Turnbull said the company had "completely transformed from a single product cancer vaccine company to a multi-product leader in immunotherapy".
Prima said the name Immutep had a strong association with LAG-3 and its founder, chief scientific and medical officer Dr Frederic Triebel, and many clinical partner associations were with Immutep, with several patents registered under the Immutep name.
Prima chief executive officer Marc Voigt said that "as the global leader in LAG-3, the name Immutep better represents our corporate identity and activities".
"As it is already embedded in our day-to-day operations, costs associated with the rebrand will be minimal so it makes both strategic and economic sense," Mr Voigt said.
The company said that subject to regulatory approvals, the ASX code would be IMM and the new Nasdaq code would be IMMP.
Prima was unchanged at 2.4 cents with 2.7 million shares traded.

NEUREN

Neuren says that it will conduct a 20-to-one share consolidation next week.
Neuren said that the consolidation was “to remove an impediment to investment for some international institutions”.
The company said the last day of trading before the consolidation would be Monday November 20, 2017.
Neuren chief financial officer Jon Pilcher told Biotech Daily that as a New Zealand-based company, Neuren did not need shareholder approval for the consolidation.
Neuren was up 2.5 cents or 17.9 percent to 16.5 cents with 25.3 million shares traded.

THE HYDROPONICS COMPANY

Hydroponics says it will release 4,500,000 shares and 2,250,000 options from ASX escrow on November 30, 2017.
Hydroponics said that it had a total of 104,100,000 shares on issue including all restricted securities.
Hydroponics climbed 20 cents or 30.8 percent to 85 cents with 6.2 million shares traded.

NOXOPHARM

Noxopharm has requested a trading halt pending the release of an announcement “regarding the [Georgia NOX66] clinical trial data”.
Trading will resume on November 21, 2017 or on an earlier announcement.
Noxopharm last traded at 64.5 cents.