Biotech Daily

Friday November 29, 2024

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.1 percent on Friday November 29, 2024, with the ASX200 down 8.1 points to 8,436.2 points. Twenty-two of the Biotech Daily Top 40 companies were up, 10 fell, seven traded unchanged and one was untraded.

Yesterday's 20.9 percent worst, Paradigm, was today's best, up six cents or 13.2 percent to 51.5 cents, with 6.2 million shares traded. Syntara climbed 12.0 percent; Starpharma was up 9.5 percent; Cyclopharm climbed seven percent; Opthea was up 5.9 percent; Telix improved four percent; Actinogen was up 3.85 percent; 4D Medical, Amplia, Impedimed, Medical Developments and Prescient rose two percent or more; Avita, Compumedics, Emvision, Immutep, Mesoblast, Polynovo and Pro Medicus were up one percent or more; with Clarity, Clinuvel, EBR and Nanosonics up by less than one percent.

Universal Biosensors led the falls, down 1.5 cents or 11.5 percent to 11.5 cents, with 16,667 shares traded. Curvebeam lost 8.3 percent; Micro-X fell 3.5 percent; Imugene and Proteomics shed more than two percent; Alcidion, Cochlear, CSL, Genetic Signatures, Neuren and Resonance were down one percent or more; with Aroa and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: ONCOSIL MEDICAL

By TIM BOREHAM

ASX code: OSL

Share price: 0.8 cents; **Shares on issue:** 4,474,080,162; **Market cap:** $35.8 million

Chief executive officer: Nigel Lange

Board: Douglas Cubbin (chair), Mr Lange, Dr Gabriel Liberatore

Financials (September quarter 2024): customer receipts $63,000, net cash outflows $3.2 million, cash balance $4 million (ahead of circa $8 million capital raising).

Identifiable major shareholders:* Pengana Capital 11.97%, Sarah Cameron 5.55%, Bannaby Investments 2.88%, My Consulting Pty Ltd 2.4%, Alua Capital 2.03%, Structure Investments (Rogers family) 1.835, Peter Hall 1%
***** Except for Pengana Capital, these numbers are ahead of the capital raising.

The targeted radiation oncology outfit has the common shortcoming of falling way behind its clinical and commercialization targets. For instance, the company promised European Union approval in 2013 and finally won this assent in April 2020.

"The company has been around for a long time, but it hasn't accomplished as much as it should have," says CEO Nigel Lange, a Berlin-based Canadian who has lived in Germany for 21 years.

"We didn't have the right skills in certain areas and I needed to define where the deficiencies were."

The eponymous Oncosil device delivers a targeted radiation treatment for local unresectable (inoperable) pancreatic cancer and, so far, has been used on more than 200 patients.

Currently the device is approved for sale in more than 30 countries including the European Union, Britain, Turkey and Israel, with initial commercial treatments undertaken in Spain, Italy, Israel, Greece and Turkey.

Crucially, the company is also working on an abbreviated method of US entry.

"We are now on the cusp of moving this thing in the right direction," Mr Lange says.

Mr Lange worked at Sirtex, which commercialized a targeted liver cancer treatment before being taken over in 2018 for $1.9 billion, after a spirited takeover battle.

Mr Lange launched both Sirtex's US and then European operations and was interim CEO months for seven months after CEO Gilman Wong was embroiled in an insider trading scandal. And before Sirtex, he launched a rival liver cancer product called Therasphere.

The story to date

A novel brachytherapy for pancreatic and liver cancers, Oncosil's treatment involves irradiating tumors with a targeted intra-tumoral injection of liquid phosphorous-32. This is done under endoscopic ultrasound guidance, combined with chemotherapy. While the procedure takes merely half an hour, the localized radiation is emitted for three months.

Oncosil evolved from the listed Neurodiscovery, which was into electrophysiological assays - or something like that - before acquiring the current technology via the cash-scrip purchase of the UK Enigma Therapeutics in early 2013.

Previously known as Brachysil, the therapy was invented by biotech man-about-town Dr Roger Aston and owned by the listed Psivida (now Eyepoint), which Dr Aston co-founded.

In 2014 chair Martin Rogers departed, with Dr Aston assuming that role. He in turn was replaced by Dr Chris Roberts, the former head of Cochlear, and Sirtex chair until 2012.

Dr Aston and Dr Roberts left the building in 2021, while prominent fund manager Peter Hall could not accept a board seat this year for personal reasons.

Mr Lange joined Oncosil in 2020 (in the depths of Covid) to run Europe, when Dr Roberts tapped him on the shoulder for the top job.

Don't spare the scalpel

The Oncosil device is currently approved for unresectable locally-advanced pancreatic cancer, in combination with chemotherapy (mainly gemcitabine based).

The idea is not to cure the cancer but reduce the tumors to the point where they are operable.

"Surgery is always the gold standard," Mr Lange says.

The company estimates 10 to 15 patients of 100 can go to surgery, while 30 to 35 percent are locally advanced unresectable pancreatic cancer. The remainder have already metastasized and have few treatment options available.

Prior to receiving Oncosil, patients undergo induction Gemcitabine chemotherapy for one month. Two to three days after completion, the patient undergoes their Oncosil treatment and about three days later they resume normal chemotherapy.

Data from Oncosil's earlier 42-patient Panco study showed the treatment 'down-staged' 24 percent of the subjects to the point where their tumors could be operated.

This compared with around 10 percent of patients subject to chemotherapy, or chemotherapy plus external beam radiation or stereotactic body radiation therapies.

These treatments require frequent visits to hospital, while Oncosil is a one-time treatment delivering nearly twice the radiation.

Don’t TRIPP up on choice of chemo

In addition to deploying gemcitabine chemotherapy, the company’s current study uses the chemotherapy Folfirinox - a cocktail of multiple chemotherapy agents. Dubbed TRIPP FFX, the study is being run by the University of Verona’s dedicated pancreatic centre. Folfirinox is the favored chemotherapy regimen in Europe, because every component of the ‘cocktail’ is fully generic - that is, cheaper - and the results are better.

As of mid-November, the trial was 59 percent recruited with study completion expected by September next year.

The company’s second trial relates to how the device is administered.

Currently the procedures are done under endoscopic ultrasound guidance, which requires general anaesthesia. Based at Amsterdam’s Medical Centre (AMC), an investigator-initiated trial called Pancosil is evaluating percutaneous administration of the device for feasibility and safety. This means application via the abdomen, which can be performed in a much shorter period of time under CT (computed tomography) guidance.

“The patients are under conscious sedation, with the procedure lasting 15 to 20 minutes rather than an hour and a half for the endoscopic ultrasound-guided procedures,” Mr Lange says.

The trial is 70 percent recruited (14 of the targeted 20 patients) and as of June this year, five had been treated. AMC is Europe’s biggest recruiter of pancreatic cancer trial patients, which helps with the recruitment efforts.

Plucking the low-hanging fruit

The company has navigated tighter European rules governing medical devices, prompted by a French medical scandal involving exploding breast implants.

With Oncosil approved Europe-wide, the company is focusing on the low-hanging fruit.

“Spain has been the first one out of the gate [with 30 patients treated to date],” Mr Lange says. “Phosphorous-32 is not a widely used isotope. Most Spanish sites have their [nuclear medicine] licence and so didn’t have to re-apply.”

Some Italian hospitals are expected to start using the device shortly and the company is getting doses into Israel, on Israel’s carrier EL Al from Frankfurt.

“Generally, in the larger markets we employ a direct sales force, but in the smaller markets we work through another company known as a distributor where it makes little sense - from a return on investment perspective - to employ our own people,” Mr Lange says.

Last week Oncosil tied up distribution deals covering the searing expanses of Egypt and the icy Nordic climes (Sweden, Denmark, Norway, and Finland). Earlier the company struck distribution compacts in the Gulf States, Saudi Arabia and Portugal.

Entering the US through the back door (no, not via Mexico)

As always, the US market is the big prize, but the cost of entry is prohibitive.

“For locally-advanced pancreatic cancer, we would need to do a large randomized, controlled pivotal trial which would take a long time and a lot of money,” Mr Lange says. “Even to show a small difference in overall survival you need a lot of patients.”

Instead, the company plans to tap its humanitarian device exemption (HDE) status for distal cholangial carcinoma (DCCC) – better known as bile duct cancer. HDE - which allows for reimbursement - is limited to a disease with fewer than 8,000 US patients (there are about 1,500 DCCC sufferers in the US).

DCCC tumors are especially tricky because the worm-shaped growths can form in different places, wrapped around the bile duct. This makes it harder to apply the dose evenly.

Jet-setting isotopes

Oncosil’s doses accrue more frequent flyer miles than a pollie on the hustings. Fortunately, phosphorous-32 is a “forgiving” isotope with a 14-day half-life.

“If you miss a flight, it is not an issue at all,” Mr Lange says. “The hospital can generally treat the patient within a nine-day window, which is a big advantage.”

Currently, the microparticle material is sourced as a powder and is shipped to Germany, where it is placed in a special ampoule and then a canister.

The canister is shipped to Australia where it is placed in the Australian Nuclear Science and Technology Organisation’s (ANSTO’s) reactor, at Lucas Heights in western Sydney, for two weeks of ‘cooking’.

The ampoules are shipped to Germany, where patient doses are produced and dispatched to hospitals.

However, the company is starting a secondary fully-automated manufacturing facility at Macquarie Park, just down the road from Lucas Heights.

Mr Lange says the site will ensure production and enhance supply chain robustness should the German plant go off line.

Finances and performance

In late October Oncosil replenished its coffers with a capital raising of up to $8 million, $7 million via an institutional placement and up to $1 million from a share purchase plan (SPP).

Both were struck at one cent, a 23 percent discount to the prevailing price.

The placement and share plan include one option for every share issued, exercisable at 1.5 cents up to three years from issue date.

In July, Oncosil raised $2.7 million in placement that introduced Pengana Capital as a 12 percent shareholder.

In the June half, Oncosil raised $6.8 million in a placement and rights offer.

At the end of September, Oncosil held cash of $4 million, having burnt $3.2 million in that stanza.

Over the last 12 months Oncosil shares have lairized between 0.4 cents in late June 2024 and 2.0 cents in late September this year. The shares peaked at 24 cents in January 2016.

Dr Boreham's diagnosis:

The 12th most common cancer in men and eleventh in women, pancreatic cancer remains the deadliest form of tumor and has eluded effective treatments.

About 500,000 new pancreatic cancer cases are detected each year, with a median survival of 8.5 months. Only 12 percent of patients will last five years,

Oncosil estimates an addressable market of 79,000 patients across its approved geographies, equating to an addressable market of $US588 million.

The company has an "aspirational target" of five to 10 percent market penetration in existing and near-term markets by 2029, implying up to 4,710 units (doses) a year.

Given its past foibles, Oncosil has carried more baggage than a travelling diva - as reflected in its lowly valuation. But the company is now in its best position to shed this historical luggage.

Investors have been promised a "catalyst rich" 2025 and 2026, including expected filings to the local Therapeutic Goods Administration in early 2025, entreaties to Argentina and Brazilian authorities and Pancosil trial top-line results due by next June.

The last word is courtesy of an Indian guru.

"Mahatma Gandhi once said that the difference between nothing and something is infinite," fundie Peter Hall said.

"Oncosil is something. It offers a treatment which has the potential to impact the lives of the hundreds of thousands of people who contract pancreatic cancer and their families and loved ones."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is a biotech non-guru who travels light.

BREAKTHROUGH VICTORIA

Breakthrough Victoria says it will provide $7.5 million in a multi-year, fellowship program for university and medical institute researchers to establish start-ups.

The Victoria Government-funded Breakthrough Victoria said the 'Breakthrough Fellowship Program' would spend up-to $150,000 per start-up, with 'fellows' to receive between $60,000 and $90,000 of the investment as a salary and the remaining funds to be used to support additional hiring or product development.

The Fund said that applicants must be current under-graduates, post-graduates, or recent graduates from a Victorian university or medical research institute and that each start-up must focus on commercializing research conducted by the founders or associated university professors.

Breakthrough Victoria said the program was expected to "establish up-to 50 new start-up companies and create at least 50 jobs, thereby nurturing entrepreneurial talent and enhancing future investment pipelines".

The Fund said that applications would be "evaluated on the commercial potential of the research, co-investment from university or industry partners, the founder's prior start-up experience or participation in entrepreneurship programs, and a business plan demonstrating the ability to reach critical investment milestones".

Breakthrough Victoria said that the program was "the first in Australia to offer a tangible salary and research commercialization funding, alongside mentoring and skills development".

Breakthrough Victoria acting chief executive officer Lauren Morrey said the fellowship empowered "recent graduates to dive into entrepreneurship right after graduation".

"This program bolsters Breakthrough Victoria's strategy to back high-potential research and ensure it doesn't lose momentum in the critical early stages," Ms Morrey said.

UNIVERSITY OF QUEENSLAND

The University of Queensland says it has received $344,000 to fund research on a topical cream to help prevent and treat skin cancers in organ transplant patients.

The University of Queensland said that the cream contained "a novel drug that prevented the formation of skin cancer, which was discovered and developed in partnership with Uniquest's small molecule drug discovery initiative".

The University said the drug was "the only one of its kind and has the potential to prevent the formation and also treat early stages of skin cancer in organ transplant patients".

The University of Queensland said the funding was from the National Foundation for Medical Research and Innovation and would be used to advance the cream through pre-clinical development.

The University said that pre-clinical development work would allow it to investigate the depth of application to the skin and allow larger scale manufacturing down the track.

The University of Queensland said Uniquest had filed a patent on the molecule.

The University's researcher Prof James Wells said the funding was "a major step forward that we hope will allow us to take this promising molecule to clinical trials down the track".

"After receiving an organ transplant, patients have to take immune-suppressive drugs to help ensure their bodies do not reject the new organs," Prof Wells said.

"However, these drugs can increase a patient's risk of skin cancer, in particular squamous cell carcinomas and Kaposi's sarcoma," Prof Wells said.

"Patients are left with few options without risking transplant rejection, and that's why this new treatment would be life-changing for them," Prof Wells said.

TELIX PHARMACEUTICALS

Telix says it has dosed first of up-to 82 patients in its phase III trial of TLX250-CDx positron emission tomography imaging for clear cell renal cell carcinoma.
In an email not released to the ASX, Telix said the patient was dosed and imaged at China's Beijing Cancer Hospital.
The company said the multi-centre, phase III registration trial in China was "intended to bridge to Telix's global phase III … trial, which met all co-primary and secondary endpoints, including showing 86 percent sensitivity and 87 percent specificity, and a mean positive-predictive value of 93 percent" for carcinoma.
In 2022, Telix said a 300-patient, pivotal, phase III trial showed TLX250-CDx met its primary endpoint with 86 percent sensitivity and 87 percent specificity; and last year, said TLX250-CDx could detect extra-renal lesions, supporting potential clinical use for metastatic or recurrent cancers (BD: Nov 7, 2022; Jun 28, 2023).
Today, the company said the trial was being conducted with its Chinese partner Grand Pharma to show "the diagnostic utility of TLX250-CDx is equivalent in Chinese and Western populations".
Telix said that clinical data was "intended to support future marketing authorization applications for this breakthrough technology".
Telix chief medical officer Dr David Cade said dosing and imaging a first patient in the trial was "a significant milestone for Telix and our partner Grand Pharma".
Telix was up 96 cents or four percent to $24.74 with two million shares traded.

TRYPTAMINE THERAPEUTICS (FORMERLY EXOPHARM)

Tryptamine says it has dosed all three obese participants in its phase Ib study of the psilocybin-based intra-venous TRP-8803, with results expected by the end of the year.
Last month, Tryptamine said its 11-healthy volunteer, phase Ib trial showed TRP-8803 was "generally safe and well-tolerated" (BD: Oct 18, 2024).
Last week, the company said the phase Ib study confirmed the required dose for a phase II trial but did not state the specific dose (BD: Nov 19, 2024).
Later, Tryptamine said it had dosed and discharged the first of three obese participants in the phase Ib study (BD: Nov 22, 2024).
Today, the company said "each subject progressed through the treatment well and were safely discharged shortly after study completion".
Tryptamine said that results from the study were expected "to be received prior to the end of the year and will support the potential application of TRP-8803 to achieve improved health outcomes in obese study participants".
The company said the results would "provide additional valuable and cost-effective data to optimize dose selection for the company's phase II clinical program using TRP-8803 in specific indications".
Tryptamine said phase II clinical program planning was "well advanced, and further updates are expected over the coming months".
Tryptamine chief executive officer Jason Carroll said that completing "subject dosing over such a short timeframe is a great achievement and also highlights the considerable potential for future research opportunities using TRP-8803".
"All subjects that underwent treatment did so safely and were all discharged after the administration, marking the achievement of an important early-stage clinical objective and also confirming the potential of TRP-8803 to deliver improved health outcomes in a timely manner," Mr Carroll said.
Tryptamine was up 0.1 cents or 2.3 percent to 4.4 cents with 3.5 million shares traded.

ALGORAE PHARMACEUTICALS (FORMERLY LIVING CELL TECHNOLOGIES)

Algorae says pre-clinical studies of its drug candidate AI-168 show “strong cardio-protective qualities, outperforming existing first-line … beta-blockers”, in-vitro.
Algorae said AI-168 was a fixed dose combination drug combining a cardio-selective beta-blocker with cannabidiol (CBD)” one of the active ingredients in marijuana.
The company said pre-clinical assessments were conducted with Melbourne’s Monash University Victorian Heart Institute “to further assess the formulation of AI-168 and compare the performance of AI-168 with beta-blockers using well-established in-vitro models of cardio-vascular disease”.
Algorae said the studies used three cardio-vascular cell lines, including human umbilical vein endothelial cells, human pulmonary artery smooth muscle cells and rat cardio-myoblasts to assess the dysregulation of cell growth caused by cardiac stressors.
The company said that it would continue to assess AI-168 “for use in medical indications in which beta-blockers are commonly prescribed”.
Algorae said the results would “be used to identify the most appropriate in-vivo models of cardio-vascular disease, which Algorae is evaluating in conjunction with the Monash University researchers”.
The company said it had filed a Patent Cooperation Treaty application which would allow it “to pursue patent protection for AI-168 in commercially important jurisdictions”.
Algorae was up 0.1 cents or 14.3 percent to 0.8 cents with 27.7 million shares traded.

ARGENT BIOPHARMA (FORMERLY MGC PHARMACEUTICALS)

Argent says it will delist from the London Stock Exchange (LSE) and maintain its listings on the ASX and the US Over-the-Counter Bulletin Board (OTCQB).
In 2021, the then MGC said that it had raised GBP6.5 million ($A11.6 million) at 1.475 British pence (2.64 Australian cents) to be the first medicinal marijuana company to list on the London Stock Exchange main market (BD: Feb 4, 2021).
At that time, the company said it would maintain a dual LSE and ASX listing to “significantly broaden … [its] international profile and specifically provide direct access to UK and European institutional and other investors”.
Earlier this year, MGC said 99.78 percent of an extraordinary general meeting approved its change of name to ‘Argent’; and later, said 99.7 percent of its 2024 annual general meeting backed its ASX delisting (BD: Mar 19, Apr 2, Oct 2, 2024).
In August, Argent said with Trondheim, Norway’s Sintef it would develop anti-microbial active ingredients and nano-formulations of the ingredients for the treatment of chronic wounds (BD: Aug 21, 2024).
In its initial public offer prospectus lodged to the ASX in 2015, the then MGC said it was “a medical and cosmetics cannabis company, formed in early 2015 to specifically target the global potential of the fast growing medical and cosmetic cannabis markets … [with its] unique [cannabidiol] genetics strain to maximize crop yield”.
Today, the company said it would delist from the London Stock Exchange “in an effort to streamline and simplify processes and increase administrative efficiencies”.
Argent said it expected the last day of trading on the LSE to be December 31, 2024.
The company said the delisting was not subject to shareholder approval and that it would “still look to explore opportunities to expand its accessibility to investors, including the potential for a dual listing on a US-based exchange”.
Last year, the then MGC said 96.6 percent of extraordinary general meeting votes supported a 1,000-to-one consolidation (BD: Sep 26, Oct 26, 2023).
Argent was up two cents or eight percent to 27 cents.

ORTHOCELL

Orthocell has requested a trading halt “pending an announcement … regarding the results of the regulatory study required for … market approval of Remplir in the US”.
Trading will resume on December 3, 2024, or on an earlier announcement.
Orthocell last traded at 81 cents.

GENETIC TECHNOLOGIES

Genetic Technologies administrators FTI Consulting have told the ASX that the funds raised from the company’s undersubscribed rights offer “are to be returned”.
In a query dated November 19, 2024, the ASX said that an entitlement offer prospectus announced on August 2, 2024 stated if the minimum subscription amount of $2 million was “not achieved within three months of the date of the prospectus all application money received will be refunded in full”.
The ASX noted that the entitlement offer closed on September 9, 2024 and had raised $324,648 at 4.0 cents a share in a two-for-three rights issue (BD: Sep 12, 2024).
Last week, FTI Consulting said its Ross Blakeley and Paul Harlond were appointed as voluntary administrators of Genetic Technologies (BD: Nov 20, 2024).
On Wednesday, Genetic Technologies administrator FTI Consulting said the company would refund all applications for its rights issue (BD: Nov 27, 2024).
Genetic Technologies was in a suspension and last traded at 3.9 cents.

AUSBIOTECH

Ausbiotech says it has appointed Dr Dell Kingsford Smith as a non-executive director, and Dr Megan Baldwin had been reappointed for her third term.
The industry organization said Dr Kingsford Smith was currently Cochlear Asia Pacific head of medical affairs, market access and government affairs and had previously worked for Janssen and Johnson & Johnson.
Ausbiotech said its board comprised chair Dr James Campbell, Erica Kneipp, Dr Megan Baldwin, Dr Dean Moss, Dr Marthe D’Ombrain, Prof John Skerritt, Dr Liz Dallimore and Dr Dell Kingsford Smith.

MICROBIO

Microbio says it has appointed Paul Brennan as chair and Neil Verdal-Austin as chief operating officer, both effective from December 2, 2024.
Microbio said Mr Brennan was currently the chair of Immuron and previously was Polynovo’s chief executive officer and had worked for Smith & Nephew and Ansell.
According to his Linkedin profile, Mr Brennan held a Bachelor of Science from Armidale, New South Wales’ University of New England and a Master of Business Administration from Melbourne’s Swinburne University of Technology.
The company said Mr Verdal-Austin had 30 years of experience including as chief financial officer and then managing-director of Somnomed.
According to his Linkedin page, Mr Verdal-Austin held a Bachelor of Commerce from the University of Cape Town.
In 2022, Brisbane’s Microbio said it was more than half-way to raising $3 million to commercialize its Infectid-BSI bloodstream infection test (BD: Jul 6, 2022).
Microbio is a public unlisted company.

OPYL

Opyl says its annual general meeting has passed all resolutions by 99.45 percent, but it withdrew the special resolution to change the company name to ‘Trialkey Limited’.

Last month, Opyl said the meeting would vote to change its name to ‘Trialkey Limited’, with its ASX ticker code to become ‘TRK’ and did not give a reason for the change of company name (BD: Oct 31, 2024).

Today, the company said the remaining resolutions were passed with more than 99.46 percent of the meeting in favor.

Opyl fell 0.1 cents or 3.7 percent to 2.6 cents.