Biotech Daily

Friday June 28, 2024

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.1 percent on Friday June 28, 2024, with the ASX200 up 7.9 points to 7,767.5 points. Twenty-two of the Biotech Daily Top 40 stocks were up, 13 were down and five traded unchanged. All three Big Caps were up.

Actinogen was the best, for the third day in a row, up 1.6 cents or 34.8 percent to 6.2 cents, with 38.5 million shares traded. Starpharma and Syntara were up more than nine percent; Clarity climbed 6.9 percent; Imugene improved 5.6 percent; Next Science and Percheron were up more than four percent; Micro-X and Neuren were up more than three percent; Medadvisor and Pro Medicus rose two percent or more; Amplia, Cochlear, Cynata, Impedimed, Mesoblast, Nanosonics, Resmed and Telix were up one percent or more; with Avita, Clinuvel, CSL, Genetic Signatures, Polynovo and SDI up by less than one percent.

Immutep, led the falls for the second day in a row, down four cents or 11.9 percent to 29.5 cents, with 30.6 million shares traded. 4D Medical fell 8.8 percent; Curvebeam and Emvision were down more than five percent; Alcidion, Cyclopharm and Resonance fell four percent or more; Atomo was down 3.85 percent; Opthea, Prescient and Proteomics shed more than two percent; with Paradigm and Medical Developments down more than one percent.

DR BOREHAM'S CRUCIBLE: RADIOPHARM THERANOSTICS

By TIM BOREHAM

ASX code: RAD

Share price: 3.8 cents

Shares on issue (pre $70m capital raising)**:** 460,367,051

Market cap: $17.5 million

Chief executive officer: Riccardo Canevari

Board: Paul Hopper (executive chair), Mr Canevari, Ian Turner, Hester Larkin, Dr Leila Alland, Phillip Hains

Financials (March 2024 quarter): receipts $291,000, operating cash outflows $4.2 million, cash balance $2.93 million (ahead of circa $70 million capital raising)

Identifiable major holders: (post-capital raising) Paul Hopper 7.8%, Lantheus emerges as 6.9 percent shareholder with options to increase to 19.9 percent.

Is the 'Telix glow' finally starting to illuminate its ASX-listed peers?

We're referring of course to the stupendous success of radio-pharmacy play Telix Pharmaceuticals, which now bears a $6 billion-plus market valuation on the back of its approved prostate cancer imaging agent.

Shares in the down-in-the-dumps Clarity Pharmaceuticals started moving six months ago and last week it was the now cashed-up Radiopharm Theranostics' turn.

The catalyst for Radiopharm's Tuesday's share jump of up to 35 percent was the announcement that the company would raise $70 million of capital, by way of a $62.5 million institutional placement and an initial $7.5 million strategic investment from Nasdaq-listed radio imaging giant Lantheus Holdings.

Lantheus also relieves Radiopharm of two pre-clinical assets for another $3 million.

Put in context, the 1.7 billion extra shares boosts Radiopharm's shares on issue by 372 percent, but happily the deal was struck at a premium to the prevailing price.

Lantheus emerges with a 6.9 percent undiluted stake, but has the option to climb to 19.9 percent later on by way of $7.5 million of unlisted options and listed options on top of that.

A recent precedent bodes well: In January this year, Lantheus took a $US33 million, 19.9 percent stake in US radio-pharmacy peer Perspective Therapeutics, with Perspective shares since climbing 150 percent.

About Radiopharm

Radiopharm operates in nuclear medicine, which is about combining a molecule and an isotope to form a radioactive tracer which is then detected by scans such as positron emission tomography (PET).

Radiopharm has programs covering the use of several different isotopes with agents to target cancer biomarkers including PDL-1, HER-2, the integrin alpha V beta 6 peptide (AVB6) and the fatty acid synthase.

A creation of biotech entrepreneur Paul Hopper, Radiopharm listed on the ASX in November 2021, with assets acquired from Imperial College London, New York's Sloan Kettering Memorial Hospital and the Technical University of Munich.

Radiopharm has tweaked targeting agents and isotopes to address multiple indications, notably brain, non-small cell lung, breast, gastric and pancreatic cancers.

"The thinking was to do something different in the space … and bring innovation to the market," CEO Riccardo Canevari says.

Complementing the company's own programs, two years ago Radiopharm formed a private joint venture with the Texas-based MD Anderson Cancer Center (MDACC) to in-licence MDACC technologies. Radiopharm owns 51 percent of the JV. In pre-clinical stage, the first program is a molecule targeting B7H3 in multiple cancers. B7H3 is a biomarker, not a British motorway.

Mixing and matching

The 'theranostics' in the company's name refers to developing both diagnostic and therapeutic radiopharmaceuticals for cancer.

The diagnostic leg involves the use of low-energy radio-isotopes to allow physicians to 'see' and measure tumors. The treatment bit involves high-energy particles. The process involves attaching a low-energy radioactive isotope to a targeting agent, such as a small molecule or antibody.

"With the same molecule using different isotopes you can have an imaging agent to detect where the tumor is – both large tumors and small metastases," Mr Canaveri says. "Then you switch isotopes to get the therapeutic model going to the same place."

Targeting the brain

Radiopharm's most advanced program, RAD-101, aims to develop an imaging tool for brain metastases. It involves using the isotope F18 (not the fighter jet) and combining it with a radio-tracer called pivalate.

The target is the fatty acid synthase, which is overexpressed in cancerous brain cells but not healthy ones.

In 2022, the company reported positive results of a phase II imaging trial involving 17 patients (11 of them treatment-naïve). The gist was that the injected radiotracers migrated to the tumors effectively, which is crucial for a targeted treatment that does not zap healthy cells.

The company has submitted an investigational new device (IND) application to the US Food and Drug Administration for a phase IIb trial, targeting 30 patients, with a read-out expected by July 2026.

But what problem is the company trying to resolve?

Mr Canaveri says the standard-of-care magnetic resonance imaging (MRI) scans work quite well for the initial assessment of brain metastases. The trouble is, 70 percent of patients need treatment by way of stereotactic radiosurgery (radiation beams).

Post treatment, some tissue becomes necrotic - dead - and the MRI no longer can distinguish between the deceased area and the tumor.

The company believes its treatment can negate these problems.

Mr Canevari says there are about 300,000 new brain cancer patients in the US every year - a similar-sized market to prostate cancer and representing a $US1.25 billion-a-year addressable market.

On the competitive front, Italy's Bracco Imaging is in phase III studies using Axumin, a previous prostate cancer imaging tool, for brain cancer imaging.

So, we guess RAD-101 just has to be more effective - and management is confident it will.

Pretty RAD agenda

Based on the lutetium 177 (Lu-177) isotope, Radiopharm's RAD-204 program is for non-small cell lung cancers that express the PD-L1 target.

A phase I therapeutic trial is enrolling 27 patients in multiple Australian locations.

This program centres on genetically-engineered antibodies called nano-mabs (monoclonal antibodies), which derive from a specific breed of camel (dromedaries, we believe, but don't get the hump if that's wrong).

Also deploying Lu-177, RAD-202 targeting HER-2, mainly for patients with breast or gastric cancer. "We think we can start a trial in September and are putting together four or five clinical centres in Australia," Mr Canevari says.

With pancreatic cancer, the company has FDA orphan device indication for Trivehexin, a peptide deployed with either the gallium-68 or Lu-177 isotopes. The imaging program, RAD301, uses gallium-68 to target AVB6,, with a readout expected in late 2024.

A therapeutic program, RAD302 also targets AVB6, but with Lu-177. The next step is a phase I dose escalation trial, planned for early 2025. RAD302 has potential for other caners including head and neck, lung and colorectal.

Mr Canevari says the open-label nature of the trials can communicate on aspects such as dose escalation.

“A phase I trial might take 14 to 16 months but it is not a black hole. We will keep informing the market on progress.”

Don’t get caught in traffic

Given the half-life of isotopes can be short, logistics play a key role in the production and supply of nuclear agents.

“You don’t want your products to be stuck in a traffic jam,” Mr Canevari concurs.

He adds that with demand for isotopes soaring, it’s crucial to have a solid long-term supply contracts with the nuclear facilities producing the goodies.

In Australia the Australian Nuclear Science and Technology (ANSTO) provides the isotopes, while Isotopia and Shine Technologies do the honors in the Europe and the US respectively.

Finances and performance

The capital raising means the company is cashed up to the tune of $72.9 million and is well placed to execute its clinical programs.

Radiopharm on Tuesday said it had “firm commitments” to raise about $62.5 million in the placement at four cents a share, taking the total with the Lantheus placement to $70 million.

Lantheus also subscribes to unlisted options, exercisable at five cents that would raise another $7.5 million within six months.

The four cent shares are an 18 percent premium on the closing price of 3.4 cents on June 19; the five cent shares are at a meaty 47 percent premium.

Investors in the two-tranche placement will also receive one option for every four shares issued, exercisable at six cents each within two years. Are you keeping up?

Lantheus eventually can get to 19.9 percent by way of the placement shares and unlisted options, its options from the placement entitlement and then another swag of options - worth $2.24 million - if the placement options are exercised. Got it?

Given that only $23.9 million of the placement shares fall within the company's existing placement capacity, a shareholders' meeting will be held in early August to approve the remaining $46.1 million of shares and all options.

Subject to shareholder approval, Mr Hopper will invest $3 million in the placement.

Mr Canevari says the phase IIb brain cancer trial is likely to cost around $5 million.

"For phase III you would be looking at around $25 million, but that is still not a lot compared with a therapeutic trial that might need 600 patients."

After a trading halt was lifted on Tuesday, Radiopharm shares climbed from 3.4 cents to as high as 4.6 cents.

Since listing the shares have traded between 36 cents (December 2021) and last week's low of three cents (ahead of the Lantheus news). The shares listed at 60 cents apiece, but lost one-third of their value on the day and have never traded above the issue price.

Dr Boreham's diagnosis:

Mr Canevari says the Lantheus investment is a "solid endorsement" of Radiopharm's potential - and we're sure Lantheus had plenty of other investment options.

As Great Aunt Dora used to say before receiving her yuletide gift of sherry: "You needn't have!" before drinking it, anyway.

A key benefit of developing radio-imaging devices is that the proponents don't need to show their tool is better than the standard-of-care, but just as good in terms of detecting false positives and negatives.

That should bode well for near-term commercialization, but one has to be a nuclear scientist to appreciate the relative merits of the various agents and isotopes.

For glioblastoma, Lodge Partners estimates an addressable US market of 265,000 patients and an initial penetration of 10 percent. At an estimated treatment cost of $US4,730 per dose, that equates to a handy $US125 million.

Of course, rule number one of drug and device development is that market approval usually takes longer than expected.

Rule number two is that achieving market penetration takes longer than anticipated.

Rule number three is to be patient, in anticipation of rule number one and rule number two.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is also no nuclear physicist but he knows the rules and is waiting patiently for his sherry.

VICTORIA GOVERNMENT

The Victoria Government says it has awarded $2.9 million to 10 projects to help “more local researchers pursue innovative medical research projects”.

A media release from the Deputy Premier, Minister for Education and Minister for Medical Research Ben Carroll said the grants were invested through the Victorian Medical Research Acceleration Fund (VMRAF).

The Victoria Government said grants of up-to $100,000 would support early-stage innovative research projects and grants of up-to $500,000 would assist researchers “in translating their products and practices into clinical or healthcare settings”.

The Government said the grants had been awarded to 10 projects at eight institutions, including Swinburne University of Technology, La Trobe University, Monash University, Western Health, Northern Health, Melbourne Health, the Bionics Institute and the Murdoch Children’s Research Institute.

The Victoria Government said that since 2017, the VMRAF had invested more than $22 million in the State’s medical research sector “supporting 123 research projects and fast-tracking results so more patients can receive life-changing treatment”.

The Government said it had secured “more than 40 percent of the Commonwealth’s medical research funding for the ninth year in a row, more than any other state”.

Mr Carroll said the State Government was “backing local researchers like the maternal care team at Western Health, who are working hard to ensure our littlest Victorians are born safe and healthy”.

“Life-changing research doesn’t just happen overnight, it is the hard work of medical research teams who strive each day to deliver better health outcomes,” Mr Carroll said.

“Their dedication is why Victoria is a global leader in medical research,” Mr Carroll said.

More information and the full project list are available at: https://bit.ly/3L151p5.

4D MEDICAL

4D Medical says it has an up-to $30 million, three-year “at-the-market” funding facility with the Singapore-based Alpha Investment Partners.

4D Medical said that it had a “strong cash balance” of $41.2 million at March 31, 2024 and that the funding facility allowed it to raise capital incrementally at its discretion.

The company said it had agreed to place 19 million shares at no consideration to Alpha Investment Partners as collateral for the facility, which could be bought back for no consideration, subject to shareholder approval.

4D Medical said that if it did decide to use the facility the issue price would be the greater of the floor price, as set by the company, and a five percent discount to a volume-weighted average price for a period of its choosing.

The company said the facility did not preclude it from “raising capital via any other means should strategic opportunities present themselves”.

4D Medical managing-director Prof Andreas Fouras said the company was “setting in place the foundations for rapid, scalable growth”.

“We have a strong cash balance, revenues are growing strongly with additional significant upside opportunities in the short and medium term, and costs are tightly under control” Prof Fouras said.

“While the [at-the-market funding facility] is a relatively new capital management mechanism in Australia, they are widely used in the US,” Prof Fouras said.

“With this facility in place, I am confident 4D Medical won’t need to undertake any further secondary raisings to satisfy its working capital requirements,” Prof Fouras said.

4D Medical fell five cents or 8.8 percent to 52 cents with 2.5 million shares traded.

INVION

Invion says it has a $2.4 million to $6.8 million draw-down equity facility with New York's Lind Partners, with $1.2 million upfront in a share deal and a $100,000 draw-down.
The company said Lind would receive $1.44 million in shares at 0.75 cents a share if Lind subscribed before September 30, 2024, and at varying prices after, with Lind to receive 120,000,000 options, exercisable at 1.0 cent each within 30 months from their issue date.
The company said it would draw-down 11 monthly tranches of $100,000, with tranches to increase by agreement to up-to $500,000, or reduced to $25,000, in subsequent months.
Invion said Lind had the option to acquire shares for 0.75 cents each until September 30, 2024, and then had the option to buy shares at either that price or 90 percent of the average of the three lowest daily volume weighted average prices during the 20 days prior to each subscription date, limited to $70,000 a month, that could be increased to $150,000 a month, if monthly tranches under the private placements did not occur.
The company said that, from July 1, 2025, the issue price for Lind would be the lesser of 0.75 cents a share or 90 percent of the average of the lowest weighted average prices during the 20 days prior to subscription, with no purchase limits.
Invion said it would pay an establishment fee of $25,000 and 4.0 percent of each monthly tranche drawn-down, with the funds providing "greater financial flexibility as it pursues multiple development programs across a range of cancers and infectious diseases".
Invion fell 0.1 cents or 20.0 percent to 0.4 cents with 3.1 million shares traded.

ACRUX

Acrux says it has a loan of $1,487,144 from Melbourne's Radium Capital at 1.33 percent monthly interest against its expected Federal Research and Development Tax Incentive.
Acrux said the loan was 80 percent of its expected Federal Government Research and Development Tax Incentive for the 10 months to April 30, 2024 and the "short-term facility" would "be repaid later in 2024 calendar year".
Acrux said the funds would be used for working capital.
Acrux fell 0.3 cents or 4.2 percent to 6.9 cents.

ARGENT BIOPHARMA (FORMERLY MGC PHARMACEUTICALS)

Argent has requested a trading halt "pending the release of an announcement regarding a capital raising".
Trading will resume on July 2, 2024, or on an earlier announcement.
Argent last traded at a post-1000-to-one-consolidation 30 cents.

IMRICOR MEDICAL SYSTEMS

Imricor says the Dubrava University Hospital has performed a second interventional cardiac magnetic resonance (ICMR)-guided atrial flutter ablation.
Last week, Imricor said the Dubrava, Croatia-based hospital performed its first ICMR-guided atrial flutter ablation using the company's products (BD: Jun 20, 2024).
Today, the company said the Dubrava University Hospital had ordered 10 additional catheter kits for further procedures but did not disclose the commercial terms of the order.
Imricor managing-director Steve Wedan said sales goals were "focused on activating more sites each quarter and ensuring consistent procedure volume at each active site".
"This is how we start to establish a new standard-of-care," Mr Wedan said.
Imricor was up 3.5 cents or 7.1 percent to 53 cents.

RECCE PHARMACEUTICALS

Recce says its 25-patient, phase I/II trial shows intra-venous R327 was “safe and efficacious against Escherichia coli” bacteria in urinary tract infections and urosepsis.
Recce said the study dosed urinary tract infection (UTI) or urosepsis patients with 4,000mg of R327 at infusion times of 15, 20, 30 and 45 minutes, with the highest dose cohort of six patients receiving 4,000mg of R327 in a 20-minute infusion period.
Earlier this month, the company said it had dosed six-patients at the maximum dose of 4,000mg of R327 at an infusion rate of 20 minutes in the trial (BD: Jun 11, 2024).
Today, Recce said all six patients showed “a reduction in the rate of bacterial growth over time, with peak efficacy most often achieved two-to-four hours post-infusion”.
The company said “most participants demonstrated significant R327 activity in their urine samples, particularly in the first hour post-dose” which showed that R327 accumulated effectively in the urinary tract.
Recce said significant R327 activity was reported in the initial 0-to-45 minutes post-dose but extended up-to two-to-four hours post-dosing, suggesting that it maintained “its efficacy for prolonged durations, potentially enhancing its therapeutic value”.
The company said no serious adverse events were reported and the study concluded the optimal dose was 4,000mg of R327 administered over an infusion time of 20 minutes.
Recce said the study met all endpoints and it expected to conduct a 30-patient, phase II trial in more diverse populations and would “explore additional therapeutic indications”.
Recce chief medical advisor Dr Alan Dunton said “the ability of R327 to disrupt bacterial energy production so effectively and sustain its activity over several hours highlights its potential as a transformative treatment for serious and/or resistant bacterial infections including complicated UTI/urosepsis,” Dr Dunton said.
Recce was up three cents or 5.3 percent to 60 cents.

MICROBA LIFE SCIENCES

Microba says it has selected six bacteria strains for its autoimmune disease program, following the screening of 182 strains with Boston’s Ginkgo Bioworks.
In 2022, Microba said it had sent its first bio-bank samples to Ginkgo to develop microbiome-based therapies for autoimmune diseases (BD: Jun 8, 2022).
At that time, the company said Gingko would identify treatments derived from the human gut microbiome for lupus, psoriatic arthritis and certain liver diseases.
Last year, Microba said it had screened 182 probiotic strains with Ginkgo, with 36 strains progressing to the second stage of functional screening (BD: Nov 28, 2023).
Today, the company said the screening process had identified “leads which exerted potent immune-modulatory effects in multiple disease-relevant cell types”.
Microba said the next step was to assess the efficacy of the six strains in disease-relevant animal models and manufacturing for clinical trials.
Microba head of therapeutics Prof Trent Munro said the company was “at the forefront of developing precision microbiome therapeutics enabled by machine learning and artificial intelligence, that have the potential to help patients in need across a number of disease indications”.
“Over the past two years we have broken new technical ground with this project and probed frontier biology imparted by novel microbes derived from the human gut microbiome,” Prof Munro said.
“This approach has now allowed selection of potent lead candidates that will be progressed as therapeutics,” Prof Munro said.
Microba fell half a cent or three percent to 16 cents with 1.4 million shares traded

COGSTATE

Australian Ethical Investment says it has increased its substantial shareholding in Cogstate from 14,875,475 shares (8.58%) to 16,442,631 shares (9.63%).
The Sydney-based Australian Ethical said it bought and sold shares between February 16, 2023 and June 25, 2024, with the single-largest purchase 510,000 shares on March 31, 2023 for $745,829, or $1.46 a share.
Cogstate was unchanged at $1.12.

HERAMED

Carl Charalambous and Kyriaco Barber Pty Ltd, say they have become substantial in Heramed with 35,372,494 shares, or 5.59 percent.
Brisbane's Mr Charalambous as director and controller of Kyriaco Barber said he bought 5,372,494 shares between May 13 and June 26, 2024 for $96,676, or 1.8 cents a share, and on June 26, 2024 bought 30,000,000 shares for $300,000, or 1.0 cent a share.
Last month, Heramed said it would raise $2.35 million through convertible notes at $1 each, $350,000 in a placement at one cent a share and $50,000 from the issue of shares at one cent each to chair Tim Chapman, subject to approval (BD: May 10, 2024).
Heramed was unchanged at 2.3 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has appointed Prof Russell Dale, Prof Jennifer Frankovich and Prof Terrence Thomas as advisors to its paediatric neuro-psychiatric disorders program.
Neurotech said it had established the advisory panel following feedback from the Australian Therapeutic Goods Administration regarding a potential regulatory pathway for the marijuana-based NTI164 as a treatment for paediatric auto-immune neuro-psychiatric disorders associated with streptococcal infections (Pandas) and paediatric acute-onset neuro-psychiatric syndrome (Pans).
The company said the University of Sydney's Prof Dale worked at the Children's Hospital at Westmead, in Sydney, and was principal investigator for its Pandas/Pans clinical trial.
Neurotech said Prof Frankovich worked in the paediatrics department at San Jose, California's Stanford University and Prof Thomas was head of neurology at Singapore's Kandang Kerbau Women's and Children's Hospital and Singapore General Hospital.
Neurotech fell 0.2 cents or 2.8 percent to seven cents with 1.5 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has appointed Peter Vaughan to replace Darren Keamy as its company secretary, effective from today.
Earlier this year, Clinuvel said the then chief financial officer and company secretary Mr Keamy would resign on June 30, 2024, with Mr Vaughan appointed chief financial officer from April 16, 2024 (BD: Apr 15, 2024).
Clinuvel said Mr Vaughan's appointment would last "until August 6, 2024, when a permanent company secretary is expected to start employment".
Clinuvel was up 13 cents or 0.85 percent to $15.37 with 85,040 shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has renewed managing-director Dr Philippe Wolgen's employment agreement until June 30, 2026.

In 2022, Clinuvel said it had renewed a three-year employment agreement with managing-director Dr Wolgen until 2025 (BD: Apr 1, 2022).

At that time, the company said, Dr Wolgen's employment agreement had been simplified to include only base remuneration and annual key performance indicators rather than the performance and service length clauses common in the sector.

According to Clinuvel's 2023 Annual Report, Dr Wolgen received about $1,879,431 in fixed base remuneration in the year to June 30, 2023.

The Report said that fixed base remuneration "comprises base fees, superannuation and may include non-monetary benefits including health insurance, accommodation, relocation, travel and statutory benefits".

A spokesperson for Clinuvel told Biotech Daily that the managing-director's employment agreement "includes provision for increases related to the consumer price index".

Today, Clinuvel said the one-year extension of Dr Wolgen's employment gave it an "adequate window to identify and select a successor", and that it was using an international executive search firm as well as identifying possible in-house candidates.

The company said Dr Wolgen's remuneration was "unchanged" and that it had secured his commitment for a further year with a "retention payment" equal to 200 percent of his fixed base remuneration.

Clinuvel chair Prof Jeffrey Rosenfeld said the board was "delighted to have arrived at an agreement with Dr Wolgen to enable Clinuvel to secure his commitment to the company over the next 24 months to navigate the challenges that lie ahead and enable a smooth transition to the next generation to lead the company".

"From the moment he joined Clinuvel, Dr Wolgen has established and executed a clear strategy for the business, overseeing clinical, regulatory, and commercial success achieved by few biopharmaceutical companies worldwide, while not shying away from finding solutions to complex challenges," Prof Rosenfeld said.

"As we enter a critical period of expansion, the commitment by Dr Wolgen's to a further year gives certainty to all involved while the board evaluates the skills and experience needed for Clinuvel to continue its successful journey," Prof Rosenfeld said.