Biotech Daily

Friday November 26, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: GENETIC SIGNATURES UP 6%; NOVA EYE DOWN 7%**

*** DR BOREHAM'S CRUCIBLE: RADIOPHARM THERANOSTICS**

*** ARTRYA UP AS MUCH AS 24% ON 'OVER-SUBSCRIBED' $40m IPO**

*** CORRECTION: ACTINOGEN MEDICAL**

*** NOMINATIONS OPEN FOR $40k VICTORIA PREMIER'S AWARDS**

*** HEXIMA 'OVER-SUBSCRIBED' SHARE PLAN RAISES $1m, TOTAL $11m**

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*** IMMUTEP AGM 20% OPPOSE 3.6m CEO MARC VOIGT RIGHTS**

*** MEDADVISOR 20% OPPOSE PLACEMENT CAPACITY; PETER BENNETTO**

*** SOMNOMED AGM 14% OPPOSE REMUNERATION REPORT**

*** PERENNIAL TAKES 15% OF MICRO-X**

MARKET REPORT

The Australian stock market fell 1.73 percent on Friday November 26, 2021, with the ASX200 down 128.0 points to 7,279.3 points. Just three of the Biotech Daily Top 40 stocks were up, 33 fell and four traded unchanged. All three Big Caps fell.

Genetic Signatures was the best of the three, up seven cents or 5.6 percent to $1.315, with 96,383 shares traded. Optiscan climbed 2.6 percent and Opthea was up 0.8 percent.

Nova Eye led the falls, down three cents or 8.6 percent to 32 cents, with 48,205 shares traded, followed by the week's best, Proteomics, down 8.4 percent to $1.15, with 196,439 shares traded. Starpharma fell 7.7 percent; Actinogen lost 6.9 percent; Patrys shed 5.1 percent; Dimerix, Pharmaxis, Prescient and Resonance fell more than four percent; Alterity, Clinuvel, Compumedics, Cynata, Immutep, Imugene, Medical Developments, Nanosonics, Neuren, Polynovo and Orthocell were down three percent or more; Amplia, Impedimed, Mesoblast, Next Science, Oncosil, Osprey and Telix shed two percent or more; Avita, Cochlear, CSL, Cyclopharm, Kazia, Paradigm and Volpara were down more than one percent; with Pro Medicus and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: RADIOPHARM THERANOSTICS

By TIM BOREHAM

ASX code: RAD

Share price: 37.5 cents; **Shares on issue**: 253,333,557; **Market cap:** $95.0 million

Chief executive officer: Riccardo Canevari

Board: Paul Hopper (executive chair), Mr Canevari, Ian Turner, Dr Michael Baker

Financials (year to June 30, 2021): revenue nil, loss of $485,190, cash on hand $68.78 million*****

***** Post IPO ($50 million of proceeds plus $18.78 million from convertible note issue)

Identifiable major holders: Paul Hopper 35.5% Nanomab Technology 8.3%, Thorney-Tiga 2.3%, Mr Canevari 1.6%.

He's baaack!

Fresh from listing immune-oncology play Chimeric, Paul Hopper can add Radiopharm Theranostics to his rota after the nuclear medicine play listed on the ASX yesterday.

The country's busiest life sciences entrepreneur has now been responsible for founding or seeding six cancer-related, ASX-listed outfits, the other four being Imugene, Kazia Therapeutics, Prescient Therapeutics and Patrys Ltd. He also chairs the spray mist drug delivery house Aravella Therapeutics, formerly Suda Pharmaceuticals.

Mr Hopper says he didn't know much about targeted radio isotopes but his interest was piqued by the 2018 listing of Dr Chris Behrenbruch's Telix Pharmaceuticals. And in 2019, Novartis bought Advanced Accelerator Applications for $US3 billion ($4.1 billion) and then six months later snaffled Endocyte for $US2 billion.

"There was an outbreak of takeover activity and I thought this could be an interesting sector," he says.

As its contrived 'theranostics' moniker implies, the company is developing diagnostic and therapeutic radiopharmaceuticals for cancer. The diagnostic leg involves the use of low-energy radio-isotopes to allow physicians to 'see' and measure distance in the body.

The treatment bit involves higher-energy particles. The process involves attaching a radioactive isotope to a targeting agent, such as a small molecule or antibody. The company's platform spans peptides, small molecules and monoclonal antibodies, addressing about 75 percent of the causes of death from cancer.

Yesterday's listing followed the company's $40 million raising at 60 cents apiece, which was more than twice oversubscribed.

Hop-per to it

Mr Hopper says there's a long-standing awareness of external beam imaging such as PET (positron emission tomography) and x-rays (which have been around for 80 years).

With the exception of Sirtex Medical and its targeted nuclear beads, there wasn't much awareness of internal radiation techniques such as lighting up tumors and cancer biomarkers so they can be easily seen (and treated).

"The sector was in the doldrums but now it's as hot as a stove," he says.

Mr Hopper last year tapped his vast offshore networks for suitable assets, eventually whittling a list of 34 possibilities to four (see below). Along the way he told Cornell University professor of medicine David Mozley about his plans.

"He quit his tenureship and joined me, before I even had the money," Mr Hopper says.

Prof Mozley is now Radiopharm's chief medical officer.

Mr Hopper then approached the New York-based Riccardo Canevari, chief commercial officer at the aforementioned Advanced Accelerator and former head of Novartis Oncology's breast cancer franchise.

"He said 'who are you and what are you doing?' I told him and he was intrigued and I got him as the CEO."

US nuclear imaging guru Dr Thom Tulip then tiptoed over as chief technology officer.

"In effect, I now had an expert due diligence committee to sift through the assets," Mr Hopper says.

Owned and funded by Mr Hopper, Radiopharm incorporated earlier this year. The board includes Dr Michael Baker, whom Mr Hopper installed as CEO at Suda.

What's all the fuss about?

In a nutshell, the company has five phase II trials and two phase I trials underway, with 133 patients dosed across three of the four assets to date. So, it's not going to die wondering.

The technology platforms are not related, having been licenced from the Imperial College London, New York's Sloan Kettering Memorial Hospital and the Technical University of Munich. The various 'bits' of the tech were invented by Prof David Ulmert, Dr Hong Ting, Prof Johannes Notni and Prof Eric Aboagye - "accomplished scientists of international renown in the radio-pharmaceutical community."

Mr Hopper and these luminaries have never met face-to-face but were due to meet in London this weekend to pow-wow in the flesh for the first time.

Covering peptides, fatty acids and antibody agents, the platforms are:

Nano-mabs

The quirk of these genetically engineered antibodies is that they derive from camels, not just any old dromedary but from a particular herd in China.

The brainchild of Dr Ting, formerly of the Oxford University, GE Healthcare and the Shanghai National Technology Centre, the antibodies that can be paired with radio-isotopes to diagnose and treat specific cancers expressing the HER-2, TROP-2, PD-L1 and PTK7 receptors.

Carried out at Shanghai General Hospital and in Germany, the company has phase I and II Nano-mab trials underway for both diagnostic and therapeutic applications in gastric, breast and lung cancer solid tumors.

Phase I imaging of 33 patients has been done and dusted, with results “indicating potential for use as whole [of] body assessment and treatment of HER-2”. A compassionate use study is expected by the end of 2021.

Pivalate

A radio-tracer rather than a ballet pirouette, pivalate is a short-chain carbohydrate with claimed superior performance over positron emission tomography (PET) imaging for prostate and brain cancers.

Also known as the clunky RPT 18F-FDIA, the tech was invented by Dr Aboagye of the Imperial College London.

Relative to PET scanning, Pivalate showed “superior imaging” with prostate and brain cancers and it was “equally good” for two breast cancer models.

A phase I trial for glioma (a type of brain cancer) is complete. Phase II will focus on renal, glioma, cerebral metastases and other solid tumors.

Av (beta) 6 integrin

Not an outdated video format but a “strong selective ligand” that targets the surface protein known as the Av(beta)6 integrin.

Evidence suggests it is over-expressed in pancreatic, cervical, head and neck and certain lung cancers.

A 10-patient compassionate use study for head and neck cancers is underway in Germany, where the compassionate use pathway, outside formal trials, is more amenable. This resulted in nice crisp images: “so nice in fact that the European Journal of Nuclear Medicine had it as image of the month in May”.

Formerly of the Technical University of Munich, Prof Notni can take the credit for this one.

PSA-MAB

The brainchild of the University of California Los Angeles (UCLA) and Essen University's Prof Ulmert, this one is a humanized monoclonal antibody targeting prostate specific antigen (PSA) in prostate cancer cells.

While in pre-clinical stage, work to date points to tumor regression and a significant increase in median survival time. Mr Hopper notes that Prof Ulmert sold an earlier iteration of the antigen to Janssen for a cool $US100 million.

Finances and performances

Mr Hopper is not short of a quid which means he was able to fund the purchase of the assets himself. The assets were acquired for $5 million to $10 million each, in a mix of cash and equities. The vendors also receive "industry standard" milestone payments and royalties of around five per cent.

In August, the company raised its first external funds: $US20 million by way of a convertible note issue, upsized from the intended $US15 million. Post-listing, the company has circa $68 million of cash on hand, which will be mainly used to support trial activity.

Peering at the ASX peers

Telix listed in November 2017, raising $50 million at 65 cents apiece to develop diagnostics and treatments based on molecularly targeted radiation (MTR).

A relatively new discipline, MTR allows radio-active isotopes to be delivered via Telix's patented molecules in a selective way, so that they only reach the tumors in question. This year, the company filed a European marketing application for its prostate cancer imaging agent and is also preparing a US entreaty.

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

Clarity Pharmaceuticals listed in late August this year, raising $92 million in the biggest IPO in ASX biotech history, so far. Clarity aims to achieve "superior imaging and highly precise and accurate therapy" using two radio-isotopes: copper-64 and copper-67.

The former is for improved PET (positron emission tomography) scanning and the latter is for, like, actual therapy. At the heart of Clarity's technology is a stable functional 'cage' called a chelator, which prevents the leakage of copper into the body. The cage is linked to a targeting molecule, which finds and binds specific receptor cancer cells.

Clarity has diagnostics and therapies for breast and prostate cancer and neuroblastoma.

Then there's Cyclopharm, whose Technegas lung imaging product is sold in 55 countries. The Technegas process involves the patient breathing radioactive particles that, when ensconced in the lung, are read by traditional imaging equipment.

While Technegas is the diagnostic of choice for pulmonary embolism, it's not yet approved in the US even though regulators across the border in Canada have no problem with it.

We should also mention erstwhile ASX listee Sirtex, which encountered clinical and other setbacks before being acquired by China Grand Pharmaceuticals for $1.9 billion, after a spirited three-way takeover tussle.

China Grand has invested in Telix and has an option to take a significant stake in Clarity.

Lastly, we have the struggling Oncosil which is pursuing Sirtex-like internal radio-therapy for pancreatic cancer. In October, chair Dr Chris Roberts of Cochlear fame left the board with fellow director Mike Bassett; with founder and technology co-inventor Dr Roger Aston also leaving the building. The company is in the hands of former Sirtex executive Nigel Lange, with Otto Buttula as chair.

Dr Boreham's diagnosis:

Radiopharm cites estimates of a $US6.7 billion market in 2020, forecast to grow to $US11.5 billion by 2027 (a compound annual growth rate of eight percent)

A pertinent question is what patient benefit is brought to the table that has not been covered by the likes of Telix, Clarity or the acquisitive overseas big boys.

Mr Hopper says Radiopharm doesn't "pretend to be the best" because it doesn't have to be: the sector is so big that there's plenty of room for all.

"If I could do as well as what Chris [Behrenbruch] has done at Telix I would be delighted," he says. "None of it really overlaps."

Since Novartis's big dive into the sector, others have followed.

"Big pharma companies are sitting on the sidelines, waiting to see if radio-pharmaceuticals become the next big thing, a la immune-oncology or checkpoint inhibitors," Mr Hopper says. My marketing intelligence is that there's going to be some more big pharma moves into the sector."

At the risk of stating the obvious: the road to approval is an arduous one, although proving up the technology for diagnostics use paves the way for an easier path to therapeutic approval. With Radiopharm shares diving 25 percent on listing, investors may have to wait awhile before dragging sack-loads of dough to the banks in the same way as Viralytics holders did. (It's now the stuff of biotech legend that the Hopper-chaired immune-oncology play was taken over by Merck for $502 million in 2018).

"You can start off with great expectations but you don't necessarily end up where you want," he says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Still, he ended up where he wanted – more or less.

ARTRYA

Artrya opened 7.4 percent above its $40 million initial public offer price of $1.35 to list on the ASX to develop and market its Salix coronary artery analysis software.

Artrya opened at $1.45 on the ASX under the code AYA following an “over-subscribed” offer at $1.35, dipped to a low of $1.37 and climbed as much as 24.1 percent to $1.675.

The Perth-based Artrya is developing the Salix system to detect difficult to see plaque deposits on x-ray computed tomography (CT) images (BD: Nov 12, 2021).

The company previously told Biotech Daily that the technology had been included on Australian Register of Therapeutic Goods as a class 1 medical device, but was yet to be commercialized.

Artrya said that it had been accepted “as a supplier of artificial intelligence software and platforms” for the UK National Health Service Shared Business Services Framework, with sales expected in mid-2022.

The company said it had lodged approval submissions to the US Food and Drug Administration and European and UK device regulators.

Artrya said that the purpose of the offer was to provide access to capital markets to improve financial flexibility; develop a market for the shares and an opportunity for others to invest in the company; and increase its profile as a listed entity.

The company said the funds raised in the offer would go to clinical, research and development and regulatory programs, product development, sales and marketing as well as corporate and administrative costs.

Artrya said the board comprised chair Bernie Ridgeway with co-founder and chief executive officer John Barrington and co-founder and product director John Konstantopoulos.

Bell Potter Securities was the lead manager to the offer.

Artrya closed up 17.5 cents or 13 percent at $1.525 with four million shares traded.

ACTINOGEN MEDICAL

Last night’s edition incorrectly reported that the Actinogen capital raising at 13.5 cents a share was a “15 percent premium to the closing price on November 22, 2021”.

This was a moment of telepathic wishful-thinking by the Thursday Thanksgiving sub-editor, on behalf of the editor, who owns shares in Actinogen.

The article should have said that the offer price was a 15.6 percent discount to the last closing price.

The turkey has been forgiven on this occasion.

Biotech Daily apologizes unreservedly for the error.

Actinogen fell one cent or 6.9 percent to 13.5 cents with 6.7 million shares traded.

VICTORIA GOVERNMENT

The Victoria Government says that nominations have opened for the 2021 Premier’s Awards for Health and Medical Research, worth $40,000.

A media release from Victoria Minister for Innovation and Medical Research Jaala Pulford said there were five award categories: basic science researcher, clinical researcher, Aboriginal researcher, health services researcher and public health researcher.

The media release said category winners would each receive $5,000, with one winner to receive the Premier's Excellence Award and an additional $15,000.

The Government release said that applications would close on January 17, 2022 and to apply go to: https://djpr.vic.gov.au/medical-research/strengths/premiers-awards.

HEXIMA

Hexima says its “oversubscribed” share plan at 32 cents a share raised $1 million taking the total raised to $11 million.
Earlier this month, Hexima said it raised $10 million in a placement at 32 cents a share and hoped to raise up to $1 million in a share plan at the same price (BD: Nov 1, 2021).
Today, the company said the share plan was oversubscribed, with $3.2 million in applications, which would be scaled back.
Hexima fell 3.5 cents or 9.7 percent to 32.5 cents.

PALLA PHARMA

Palla says it has a $33.1 million sale and leaseback agreement for its pharmaceutical and medicine manufacturing site in Coolaroo, north of the Melbourne.
Palla said the sale resulted in an “estimated book gain” of $21.0 million, it had repaid all shareholder loans and agreed with its lender to retain access to a $5 million credit facility.
The company said it had an 18-month lease on the site with the option to extend the term for a further six months, but did not disclose the cost of the lease.
In September, Palla Pharma said that revenue for the six months to June 30, 2021, was down 42.7 percent to $7,060,872 with net loss after tax up 267.2 percent to $33,105,663, and it had cash and equivalents of $897,312 at June 30, 2021 (BD: Sep 1, 2021).
Palla fell three cents or 7.7 percent to 36 cents.

IMMUTEP

Immutep says its annual general meeting voted up to 20 percent dissent against the grant of 3,600,000 performance rights to chief executive officer Marc Voigt.
Immutep said the resolution to grant the rights to Mr Voight was opposed by 60,719,759 votes (20.05%) with 242,193,640 votes (79.95%) in favor.
The company all other resolutions including the remuneration report, the re-election of director Russel Howard and the amendment to its constitution were passed easily.
According to its most recent filing, Immutep had 850,922,801 shares on issue, meaning that the opposition towards granting performance rights to Mr Voigt amounted to 7.1 percent of the company, sufficient to requisition extraordinary general meetings.
Immutep fell two cents or 3.9 percent to 49 cents with 3.2 million shares traded.

MEDADVISOR

Medadvisor says it faced up to 20 percent dissent against the 10 percent placement capacity, with the re-election of director Peter Bennetto withdrawn prior to the meeting.
Yesterday, Medadvisor said eight-year director and former chair, Mr Bennetto, had resigned as director effective today (BD: Nov 25, 2021).
Today, the company said the resolution to approve the 10 percent placement capacity was opposed by 32,485,279 votes (19.46%) with 134,459,579 votes (80.54%) in favor.
Medadvisor said all other resolutions including the remuneration report, the long-term incentive plan and the election of directors Sandra Hook and Lucas Merrow passed easily.
According to its most recent filing, Medadvisor had 377,475,392 shares on issue meaning that the votes against the 10 percent placement capacity amounted to 8.6 percent of the company sufficient to requisition extraordinary general meetings.
Medadvisor fell 1.5 cents or 3.75 percent to 38.5 cents.

SOMNOMED MEDICAL

Somnomed says all resolutions were passed but it faced modest dissent against the remuneration report.
Somnomed said the remuneration report was opposed by 5,645,793 votes (13.96%) with 34,800,037 votes (86.04%) in favor.
The company said the resolutions to elect directors Karen Borg, Hamish Corlett and Guy Russo were passed with no votes in opposition.
According to its most recent filing, Somnomed had 82,759,315 shares on issue meaning that the votes against the remuneration report amounted to 6.8 percent of the company, sufficient to requisition extraordinary meetings.
Somnomed was untraded at $2.36.

MICRO-X

Sydney's Perennial Value Management says it has increased its shareholding in Micro-X from 62,041,316 shares (13.50%) to 67,472,215 shares (14.66%).
Perennial said it bought and sold shares between July 30 and November 24, 2021, with the single largest acquisition 4,903,527 shares for $1,500,479 or 30.6 cents a share.
Micro-X was unchanged at 30 cents.