Biotech Daily

Friday May 5, 2017

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.68 percent on Friday May 5, 2017 with the ASX200 down 39.8 points to 5,836.6 points. Sixteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and two were untraded.

Dimerix was the best, up 0.1 cents or 16.7 percent to 0.7 cents, with 4.3 million shares traded, followed by IDT up 12 percent to 14 cents and Genetic Signatures up 10 percent to 44 cents. Compumedics and Factor Therapeutics climbed more than six percent; Ellex was up 5.6 percent; both Airxpanders and Prana were up 3.6 percent; Starpharma rose 2.7 percent; Cochlear, Impedimed, Opthea, Orthocell, Osprey and Universal Biosensors improved more than one percent; with Medical Developments, Pro Medicus and Resmed up by less than one percent.

Polynovo led the falls, down two cents or 8.7 percent to 21 cents with 865,985 shares traded. Bionomics lost 7.25 percent; Actinogen, Living Cell and Oncosil fell four percent or more; Cellmid, Prima and Sirtex were down more than three percent; Mesoblast and Uscom shed more than two percent; Acrux, Admedus, Nanosonics and Pharmaxis were down more than one percent; with Clinuvel, CSL and ITL down by less than one percent.

DR BOREHAM'S CRUCIBLE: ONCOSIL MEDICAL

By TIM BOREHAM

ASX Code: OSL

Market cap: $56 million; **Share price:** 12 cents; **Shares on issue:** 468.5 million

Chief executive officer: Daniel Kenny

Board: Dr Chris Roberts (chairman), Dr Roger Aston, Daniel Kenny, Dr Martin Cross

Financials (March 2017 quarter): revenue nil, operating cash outflow ($2.1 million, nine months year-to-date $13.9 million), cash $9.44 million (previously $11.55 million), estimated current quarter cash outflow $2.3 million.

Major shareholders: Regal Funds Management 9.7%, Webinvest 6.4%, management and directors 14%.

Oncosil chief Daniel Kenny is upfront about the company's reputational problems which have dragged the shares down from their high watermark of 24 cents in January last year.

He insists Oncosil, which is developing an implantable radiotherapy medical device for pancreatic and liver cancer, has changed its spots after a board cleanout.

"Old management over-promised and under-delivered," says Mr Kenny, who joined in early 2015.

A subsequent board rejig saw the departure of chairman Martin Rogers and the arrival of Dr Chris Roberts, who had just stepped down from his long-standing role as head of Cochlear.

Dr Roberts this week was anointed chairman, and given his long interest in radiation pharmacy, we'll assume he wasn't motivated by the modest stipend for being the company's titular head.

Four of Oncosil's executives are ex-Sirtex and that doesn't include Dr Roberts, who used to chair the targeted liver cancer radiotherapy house up to 2004.

A mini Sirtex?

For better or for worse, Oncosil has been presented as a mini-me version of the $900 million market cap Sirtex, which diligent Biotech Daily readers will know has been in it deeper than a Werribee canard.

While both companies target liver cancer, Oncosil's focus is on the $US1 billion market for pancreatic cancer, the sixth most common cancer and a bugger to treat.

The treatment involves the carrier particles containing the soft radiation being suspended in fluid and injected directly, through an endoscope, into the tumor. The procedure takes half an hour under anaesthetic, with the localized radiation emitted for around three months.

Across Oncosil's target markets, 90,000 patients are diagnosed with pancreatic cancer each year, and it has one of the worst mortality rates of all cancers. Prognosis is poor even with treatment, with a median survival period only eight months.

Liver cancer is Oncosil's slow burn indication. If it is ever approved, it will not compete with Sirtex, because Oncosil is better suited to small tumors. It's more likely to compete with external radiation ablation therapy.

Regulatory progress:

The company promised Conformité Européenne (CE) mark in 2013 but the timeline proved ambitious, to say the least.

Finally, in October 2015, the regulator approved the application for the pancreatic cancer indication – on the proviso the company provides supplemental data from 20 advanced pancreatic cancer patients to support the existing safety and clinical data.

"The market has failed to appreciate what a significant achievement it is," Mr Kenny says. "It is hard to get approval for a class three radioactive device."

An application for US investigational device exemption (IDE) was granted in July last year, which like Mussolini's trains, was bang on schedule.

IDE status allows Oncosil to carry out a clinical study and – lo and behold – contract partner Monash Health a week ago treated the first patient for the 300-patient global trial, which seeks to establish Oncosil as a first-line therapy for patients diagnosed with locally advanced pancreatic cancer.

The Oncopac-1 trial will randomize patients to either Oncosil's Brachysil bio-silicon radiation treatment with Folfirinox chemotherapy; or Brachysil with gemcitabine and nab-paclitaxel (known as Abraxane) chemotherapy; or chemotherapy treatment alone.

Mr Kenny says some investors also misunderstood the European authorities demand for the 20-patient data as an onerous burden. "It does not involve a new trial but a subset of data from the existing trial in place for the FDA IDE," he says.

Trial progress:

To date, Oncosil has completed four studies, two for liver cancer and two for pancreatic cancer.

Most significant was a phase IIa safety study of 17 patients with locally advanced pancreatic cancer, treated with Oncosil and gemcitabine.

The results showed a reduction in tumor volume in 13 of the 16 patients - an 81 percent 'pass' rate - with a median progression-free survival of 121 days and overall survival of 309 days.

Management expects to have the additional data by the end of September, with CE mark expected by the end of 2017 and sales in the UK, EU and Australia in 2018.

Oncosil expects to lodge a pre-market approval submission to the US Food and Drug Administration in 2020.

Chief financial officer Tom Milicevic estimates a full FDA trial at $US18-20 million, which will be funded … somehow.

Dr Boreham's diagnosis:

With a $56 million market cap, Oncosil has traded in a share price range of eight cents to 23 cents over the last 12 months.

Oncosil's March quarter statement showed a cash burn of $2.1 million, with $2.3 million expected to be expended in the current quarter.

Oncosil sits on cash of $9.4 million, having raised $10 million in a placement to Regal Funds Management in February last year.

The company has no plans to go to the well again, but if someone were to offer a fistful of dollars it would be impolite to refuse.

The global trial is being supported by drug company Specialised Therapeutics, which is kindly providing a free supply of Celgene's Abraxane.

At $30,000 to $40,000 a pop for the eight to 10 local patients, that's better than a kick in the pancreas.

The misunderstood Oncosil has suffered from a bout of West Coast-itis, a virulent investor malaise reflecting the company's origins as a back-door listing through the tortured Perth-based Neurodiscovery, which caused shareholder agony by failing to commercialize drugs for neuropathic and dental pain.

However Oncosil's operations have always been Sydney-based and management would struggle to tell the difference between Freo and Rotto.

With the esteemed Doc Roberts on board, here's hoping for happier times for the company's 2,800 patient shareholders.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But like all tortured geniuses, he is profoundly misunderstood.

FEDERAL GOVERNMENT AUSTRALIAN RESEARCH COUNCIL

The Federal Government says $3.7 million will be allocated to Australian Research Council Linkage Projects, with just one directly related to medical research.
The Federal Minister for Education and Training Senator Simon Birmingham announced the grants, which include $360,000 for Edith Cowan University's Prof Kamal Alameh to work with Lazcath Pty Ltd "to develop a new hybrid fibre-optic radio frequency catheter system and software to assist cardiac electro-physiologists in non-invasive, microscopic lesion formation assessments.
The ARC media release said Queensland University of Technology's Prof Christopher Barner-Kowollik would receive $190,000 in a project with Polymer Standard Service GMBH to develop chromatographic materials allowing better molecular imaging.
The other eight grants related to: the histories of indigenous and settler experiences in Australasia and North America; an iron ore sintering control mechanism; low cost and scalable efficient energy windows; cryopreservation of endangered Australian rainforest species; examination of whether running shoes helped or hindered the natural spring-like function of the foot; modelling tools to predict land values more accurately; nanoscale silicon chip motion for computing performance in harsh environments; and genomic technologies to improve cow fertility.
ARC acting chief executive officer Leanne Harvey said the Linkage Projects "were considered under the continuous application and assessment process allowing researchers and industry to collaborate as opportunities arise.
More details about the Linkage Projects are at: https://rms.arc.gov.au.

OVENTUS MEDICAL

Oventus says it has lodged a US Food and Drug Administration 510k submission for its O2Vent W device for snoring and sleep apnoea.
Oventus managing-director Neil Anderson said the O2Vent W was "important to the company's … ability to meet a wide range of needs in … dental marketing".
Mr Anderson said that the company had a" significant number of dentists who have requested a 'winged' version of the O2Vent with an airway … because they are used to delivering these types of appliances to their patients."
"We have been able to quickly develop and manufacture this device in response to these requests and we are already shipping the first products to Australian clinicians for delivery to their patients," Mr Anderson said.
Oventus said that once the FDA cleared the O2Vent W, it would have three devices for sale in the US and the positive airways pressure connection, in development, would be compatible with the O2Vent W and O2Vent T for low pressure combination therapy.
The company said it expected FDA O2 Vent W approval by the end of 2017.
Oventus was up four cents or 10 percent to 44 cents.

PHARMAUST

Pharmaust says that China has approved a core patent relating to its Monepantel (PPL-1) cancer treatment for humans and dogs.
Pharmaust said that patent, entitled 'Kinase Inhibitors for the Treatment of Cancer' claimed the use of amino-acetonitrile derivatives as kinase inhibitors for cancer.
The company said that the priority date was 2013, provided the company with a minimum of 16 more years of intellectual property protection.
Pharmaust was up 0.3 cents or 5.45 percent to 5.8 cents with 1.5 million shares traded.

REVA MEDICAL

Reva says it will ask investors to approve directors' options over the equivalent of 630,000 Chess depository instruments (CDIs) and 360,000 "restricted" CDIs.
Last year, Reva's annual general meeting overwhelmingly approved the issue of the equivalent of 826,000 options and 441,000 shares to directors and increased directors' fees 50 percent to $577,905 a year (BD: Apr 20, 2016).
Last night, Reva filed a notice of meeting to the US Securities and Exchange Commission, but at the time of publication had not filed one to the ASX.
The company said it proposed to grant options over 10,500 US shares, equivalent to 105,000 Chess depository instruments (CDIs), as well as 6,000 "restricted" stock units, equivalent to 60,000 CDIs, to each of directors Dr Ross Breckenridge, Brian Dovey, Scott Huennekens, Gordon Nye, Robert Stockman and Robert Thomas.
Reva said the options would be exercisable at the price on the date of the grant, vesting in four instalments over 12 months, from three months after the grant, with no other conditions and within 10 years.
The company said the restricted stock units would vest on the earlier of one year from the date of the award or the day prior to the 2018 annual general meeting, with no performance conditions or other requirements.
Reva said shareholders would also vote to approve, on an advisory basis, the compensation of the named executive officers, as well as the issue of up to 187 convertible notes each with a face value of $US100,000, the issue of up to 841,500 options over US shares for the convertible note-holders, re-approve the issue of 250 convertible notes each with a face value of $US100,000 and issue shares on conversion under tranche 2 of the recent capital raising, ratify the tranche 1 offer of 338 convertible notes, each with a face value of $US100,000, and 1,521,000 options over US shares, and elect directors Brian Dovey and chief executive officer Dr Regina Groves.
The meeting will be held at the AGL Theatre, Museum of Sydney, Corner Phillip and Bridge Streets, Sydney on June 1, 2017, at 10:30am (AEST).
Reva was untraded at 96.5 cents.

AIRXPANDERS

Airxpanders will vote to grant chief executive officer Scott Dodson and five directors options over the equivalent of 1,349,250 Chess depository instruments (CDIs).
Last year, Airxpanders shareholders overwhelmingly voted to grant Mr Dodson and five directors options over the equivalent of 1,092,600 CDIs (BD: May 4, 2016).
Today, Airxpanders proposed that Mr Dodson be granted 10-year options over 200,000 US shares equivalent to 600,000 CDIs, exercisable at the price on the date of the grant, with 25 percent vesting at 12 months from the date of grant and the balance monthly thereafter, with 50 percent of any unvested options to vest on a change of control of the company provided Mr Dodson made himself reasonably available to the new entity.
The company said that it proposed to issue options over shares equivalent to 149,850 CDIs to each of directors Barry Cheskin, Dennis Condon, Elizabeth Hammack, Gregory Lichwart and Zita Peach, all exercisable at the price on the date of the grant, vesting over 12 months and expiring after 10 years.
Airxpanders said it would ask shareholders to approve the 10 percent placement facility and elect directors Mr Condon and Ms Hammack.
The meeting will be held at Johnson Winter & Slattery, Level 34, 55 Collins Street, Melbourne, on May 23, 2017 at 9am (AEST).
Airxpanders was up three cents or 3.6 percent to 87 cents.

BIOTECH CAPITAL

Biotech Capital says it has an exclusive license and supply agreement with the Gothenburg, Sweden-based RLS Global AB for the wound care product Chlorasolv.
Biotech Capital said that licence, through its wholly-owned subsidiary Bioimpact Pty Ltd, was effective immediately and granted the rights to distribute Chlorasolv topical gel in Australia, New Zealand and countries in the Asia Pacific region.
The company said that Chlorasolv was classified as a medical device and was “clinically proven to effectively clean and assist with the healing of chronic wounds”.
Biotech Capital said that US Food and Drug Administration and Conformité Européenne (CE) mark approvals were expected in 2018.
Biotech Capital said that the global wound care market was $US17.0 billion in 2016.
Biotech Capital was unchanged at 13 cents.

AUSCANN GROUP HOLDINGS

Auscann says it has been granted a Federal Government licence to cultivate medicinal cannabis in Australia.
Auscann said the licence was granted by the Office of Drug Control, under the Narcotic Drugs Act 1967, making it “one of a select few companies to be granted a licence” and enabling it to undertake medicinal cannabis cultivation operations in Australia.
Auscann managing-director Elaine Darby said the licence was “a major milestone for Auscann and represents significant progress in our strategy to become a leading producer and supplier of high quality medicinal cannabis to Australian patients”.
“This licence enables us to undertake cultivation of medicinal cannabis at our site in Western Australia,” Ms Darby said.
Auscann was up 10 cents or 17.2 percent to 68 cents with 5.6 million shares traded.

NUHEARA

Nuheara says its share plan at eight cents a share has raised $247,500 of a hoped-for $2,600,000, taking the total raised to $4,647,500.
In March, Nuheara said an oversubscribed placement raised $4,400,000 and it would offer a share plan for a further $2,600,000 (BD: Mar 29, 2017).
The company said in March that the placement was “corner-stoned by two large [unnamed] multinational institutional funds” and the funds would be used to fund the production and marketing of its Iqbuds sound filtering and device ear-buds.
Nuheara said that Hunter Capital Advisors was the lead manager and book-runner to the offer.
Nuheara was up 0.4 cents or 5.9 percent to 7.2 cents with 2.4 million shares traded.

IMMURON

In two filings Authentics Australia says it became a substantial shareholder in Immuron in 2014 and has increased to 10,249,998 shares or 10.11 percent of the company.
The Mitcham, Victoria-based Aunthetics said that the shares were held by it and Kenneth and Catherin Biddick (Conquest Sports Pty Ltd SFBEN Account) with 6,249,998 shares acquired on March 3, 2014 for $1,250,000 or 20 cents a share and a further 4,000,000 shares were acquired in and rights issue on July 7, 2016 for $1,000,000 or 25 cents a share.
Immuron was up 2.5 cents or 4.5 percent to 58.5 cents.

AIRXPANDERS

Airxpanders says it proposes to appoint Elizabeth Hammack as a non-executive director, replacing Tadmor Shalon, effective from the annual general meeting on May 23, 2017.
Airxpanders said that Ms Hammack had executive experience in the medical device and healthcare sector and had worked for Medtronic for more than 15 years.
The company said that Ms Hammack was previously the head of Medtronic atrial fibrillation manufacturing and operations "where she oversaw the manufacturing, operations and successful global expansion of their flagship product".
Airxpanders said that Ms Hammack's previously worked for Advanced Cardiovascular Systems, Conceptus and Heartport.

CRESO PHARMA

Creso says that non-executive director Dr Simon Buckingham will step down as a director to be a consultant, effective from June 1, 2017.
Creso said that Dr Buckingham would "assist with developing commercial plans and strategic partnerships" and would work closely with chief operating officer David Russell (BD: Apr 4, 2017).
Creso climbed 1.5 cents or 2.6 percent to 58.5 cents.