Biotech Daily

Friday April 17, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CYNATA UP 11%; ALTERITY DOWN 9%**

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*** LIVING CELL: COVID-19 STALLS PROJECTS, 25% PAY CUTS**

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*** MGC ARTEMIC COVID-19 TRIAL**

*** REGAL FUNDS REDUCES TO 12% OF OPTHEA**

*** ALLAN GRAY TAKES 18% OF IMPEDIMED**

*** PARADICE TAKES 8.6% OF IMPEDIMED**

MARKET REPORT

The Australian stock market up 1.31 percent on Friday April 17, 2020, with the ASX200 up 71.2 points to 5,487.5 points. Twenty-four of the Biotech Daily Top 40 stocks were up, 11 fell, three traded unchanged and two were untraded.

Cynata was the best, up eight cents or 10.6 percent to 83.5 cents, with 527,932 shares traded. Proteomics climbed 10.3 percent; Actinogen and Neuren improved more than nine percent; Ellex was up 8.4 percent; Dimerix and Telix were up more than seven percent; Compumedics and Opthea were up more than five percent; Clinuvel, Cyclopharm, Imugene, Nanosonics, Next Science and Resonance improved more than four percent; Polynovo was up 3.3 percent; Antisense, Genetic Signatures, Prescient and Universal Biosensors rose more than two percent; CSL, Kazia, Medical Developments and Starpharma were up more than one percent; with Pro Medicus and Resmed up by less than one percent.

Alterity led the falls, down 0.2 cents or 9.1 percent to two cents, with 1.6 million shares traded. Osprey lost 8.3 percent; Immutep fell 5.9 percent; Oncosil was down 4.35 percent; LBT, Optiscan and Pharmaxis were down three percent or more; Avita and Mesoblast shed two percent or more; with Orthocell and Paradigm down more than one percent.

DR BOREHAM'S CRUCIBLE: ONCOSIL MEDICAL

By Tim BOREHAM

ASX code: OSL

Share price: 11 cents

Market cap: $68.3 million

Shares on issue: 620,548,312

Chief executive officer: Daniel Kenny

Board: Dr Chris Roberts (chair), Daniel Kenny, Dr Roger Aston, Dr Martin Cross, Mike Bassett

Financials (December half 2019): revenue $325.00 (up 64.1%), loss of $3.4 million (previously $5.15 million deficit), cash of $6.8 million (down 12%)

Identifiable major shareholders*: Webinvest (Otto Buttula) 3.79%, Mr Kenny 3.76%, Dr Aston 2.0%, Dr Roberts 1.63%, Bannaby Investments (Keith Kerridge) 1.51%

***** Regal Funds Management held 5.49% on February 14, but ceased to be a substantial shareholder on February 19. Lumyna Investments held 7.35% and ceased to be a substantial shareholder on April 3.

Oncosil chief Daniel Kenny readily acknowledges the "me too" nature of the targeted radiation oncology play, which is seeking to emulate the success of Sirtex Medical which was taken over by Chinese interests for $1.9 billion after a spirited takeover tussle.

"We are standing on the shoulders of giants," he says.

After almost a decade (or two**) of promises, Oncosil this month achieved what it expected to secure back in 2013: European approval of its eponymous treatment for pancreatic cancer.

Approval was meant to be a dead cert - or so the company thought - but in March last year the British Standards Institute (the "notified body" or proxy regulator) declared the evidence showed "insufficient clinical benefit at this time".

But on April 1 this year, Oncosil reported the body was convinced of "significant clinical benefit" after the company re-presented the data.

Mr Kenny says while the original application essentially was unchanged, the company did a better job at explaining the clinical data and relevant literature.

"We basically just joined the dots and a CE mark came out of it," he says. "It took a long time to come but we got there in the end."

In mid-March the US Food and Drug Administration granted the company breakthrough device designation (BDD), in relation to unresectable (inoperable) locally advanced pancreatic cancers.

This followed the FDA's granting of investigational device exemption (IDE) status in 2016.

The CE mark couldn't come soon enough, given the dire prospects for pancreatic cancer patients.

Surgery is not possible in 85 percent of cases and only five percent will survive beyond five years. About 85,000 new cases in Europe are detected annually, with a further 46,000 new cases in the US.

"The prognosis in pancreatic cancer is exceedingly poor, it is a huge area of unmet need," Mr Kenny says.

"But that didn't sway the BSI. You had to show the survival benefits to justify approval."

In economic terms, Oncosil believes it's a $1 billion a year market.

Oncosil through the ages

A novel form of brachytherapy for pancreatic and liver cancers, Oncosil's treatment involves irradiating tumors from the inside by injecting micro-particles with the radioactive isotope phosphorous-32.

The procedure involves the radiation in liquid form being injected via an endoscope directly into the tumor. While the procedure takes merely half an hour, the localized radiation is emitted for three months.

"Brachytherapy is now a widely accepted treatment for cancer," Mr Kenny says. "It's always been around but in a simplistic sense, such as putting seeds into prostates. In many ways the Sirtex therapy was the breakthrough."

****** The Oncosil technology was invented in part by current board member Biotech man about town Dr Roger Aston and owned by Psivida, which he co-founded.

Formerly Neurodiscovery, in 2013, Oncosil assumed its current guise by acquiring the British outfit Enigma Therapeutics, which had in turn acquired the technology originally called Brachysil from Psivida.

A series of board rejigs from 2014 saw the departure of chairman Martin Rogers, with existing board member Dr Aston becoming chairman. He in turn was replaced by Dr Chris Roberts, who ran Cochlear for decades.

But Dr Roberts chaired Sirtex up to 2004, so has a keen interest in radiotherapy as well as hearing implants.

A front line treatment for a deadly cancer

Unlike Sirtex's 'salvage' therapy, Oncosil's studies focused on the device in the 'first line' setting in combination with existing chemotherapy. (Sirtex spent millions of dollars on trials to expand the use of its SIR-Spheres from palliative and salvage to first-line use).

Carried out across sites in Australia, Britain and Belgium, Oncosil's Panco study enrolled 50 patients, of which 42 received the eponymous treatment plus the standard of care chemo.

Oncopac, a US trial with sister protocols enrolled a further nine patients.

In essence, the results showed a doubling of median overall survival for non-resectable cases - those that can't be operated on - from eight months to 16 months.

The average tumor reduction was 40 percent, with a maximum shrinkage of 90 percent.

More importantly, the tumors of 24 percent of patients in the Panco study shrunk to the extent that they were operable, which increases survivability even if the procedure does not actually take place.

"If you are able to downstage (the tumor) to surgery with curative intent, median survival in this cohort increases to three years," Mr Kenny says.

Technically, the resection rate was more like 33 percent, but because of co-morbidities some patients were advised against the arduous surgery which takes up to 12 hours.

If the tumor is resected, the patient's chances of five-year survival leap from five per cent to 20 percent or more.

"Half the cohort is still alive even though the study started in early 2017," Mr Kenny says.

"We will continue to follow those patients to see what their outcomes are likely to be."

On your (CE) mark …

The company is now preparing for a launch in Europe on a staged basis, with applications due to be launched in other geographies that honor the CE mark.

In essence we're talking about the world minus the US, Japan and China.

Mr Kenny says Covid-19 has impacted preparations for the European launch, in that training has been bought online and access to hospitals is limited.

The company also intended to kick off in all the Western European markets but will now focus on Britain, Germany and Belgium.
The Covid-19 plagued France, Italy and Spain will have to wait.

But amid the virus pandemic, cancer therapy continues "and has to continue."

The company was aiming to launch with the hoopla of the ESMO World Congress on Gastrointestinal Cancer in Barcelona in July, which is odds-on to become an online event.

“Our best guess for launch now is October,” he says.

It takes some gall …

While Oncosil’s main focus is on pancreatic cancer, the company is also targeting bile (gall) duct cancer which is known formally by its Latin name as cholangio-carcinoma.

In December 2018, the US FDA granted the company humanitarian use designation (HUD) for the intra-hepatic and distal forms of the cancer.

Our success in pancreas showed we could treat other tumors,” Mr Kenny says. “The FDA agreed that success could be reasonably expected with distal cholangio-carcinoma.”

Mr Kenny said at a meeting with FDA reps last June, the company was encouraged to go the next step and file for a humanitarian device exemption (HDE) for distal cholangio-carcinoma.

Oncosil plans to do so next month, which means that allowing for a 75-day decision period the company could be selling in the US in 2021.

While there are only 1,500 to 1,600 cases in the US annually, distal cholangio-carcinoma is still an $US80 million ($127 million) market.

Meanwhile, Oncosil continues to work with the FDA on what it would take its breakthrough device designation for pancreatic cancer into pre-market approval.

The breakthrough designation allows for a faster and less costly route to market, with an emphasis on post-marketing rather than pre-marketing clinical data.

“We will share the specifics with the market over the next couple of months,” Mr Kenny says.

Finances and performance

A glass half-full man, Mr Kenny notes that the low-key launch will lower costs and extend Oncosil’s cash resources - $6.8 million at last count - well into 2021.

An “immediate” capital raising is not required, although this would change at the pointy end of a US approval process.

He estimates the EU market (and other countries covered by CE mark) to be worth $1 billion to $1.5 billion.

“We are targeting 10 percent market penetration within five years,” he says.

“That means $100 [million] to $150 million of sales in five years - but don’t take that as guidance.”

Mr Kenny expects reimbursement will be widely available, both from government and private insurance.

“Private payers will pay for doubling of median survival or downsizing from unresectable to resectable.”

He adds while a strategic partner would be ideal, “it is not an absolute requirement”.

Oncosil shares peaked at 24 cents in January 2016 and plumbed to a low of 4.9 cents after the March 2019 British bombshell (down 69 percent on the day).

The shares barely blipped after news of the CE mark approval hit on April Fool’s Day, this year. Then again, global markets were in serious meltdown.

Broker Bell Potter adjudges the stock to be worth 38 cents, while Wilsons’ biotech watchers reckon 43 cents is a fair price.

Dr Boreham’s diagnosis

Mr Kenny describes pancreatic cancer as a “graveyard for pharmaceutical development” with the survival rate lingering around an unimpressive five percent.

Only two pancreatic cancer drugs have been approved in the past two decades: Gemzar (gemcitabine) in the late 1990s and Abraxane (palitaxel) in 2013. These have only increased median survival by two months to 8.5 months.

Of course, Oncosil doesn’t exactly cure the cancer either, but as with so many oncology drugs it buys time for the patient and - hopefully - quality of life.

“It’s a unique and compelling technology designated as breakthrough in the US and Europe, but first we have to get out there to talk to the doctors and train the sites,” Mr Kenny says.

“In the mean-time little old Oncosil has been able to show some significant clinical milestones.”

“Little old Oncosil” has had its detractors; or perhaps it’s more a case of some investors tiring of the story.

With the European marketing approval granted and the hope of US approval, Oncosil itself may become another broad-shouldered giant.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. If he stood on the shoulders of a giant he would probably fall off and break a limb.

MESOBLAST

Mesoblast says a 60-patient, phase II chronic obstructive pulmonary disease trial shows its stem cells “significantly improves respiratory and functional … outcomes”.
Mesoblast said that administration of its remestemcel-L mesenchymal stem cells showed improvements in patients with elevated inflammatory biomarker C-reactive protein (CRP) levels, also observed in patients with various acute lung diseases, including acute respiratory distress syndrome (Ards), a complication of Covid-19.
The company said that a presentation, entitled ‘Mesenchymal Stem Cell Therapy Improves Pulmonary Function and Exercise Tolerance in Patients with Chronic Obstructive Pulmonary Disease (COPD) and High Baseline Inflammation’, had been selected for an oral presentation at the 2020 International Society of Cell and Gene Therapy meeting between May 28 and 29, 2020.
Mesoblast said the data “formed part of the clinical justification in support of Mesoblast’s submission to the US Food and Drug Administration for an investigational new drug application evaluating remestemcel-L in the treatment of patients with Covid-19 Ards”, under which it was cleared for a randomized, controlled trial of patients with moderate to severe Ards from Covid-19.
Mesoblast chief medical officer Dr Fred Grossman said the study and results of remestemcel-L for acute graft versus host disease, a condition associated with excessive cytokine release, “provided the strong rationale for the evaluation of remestemcel-L in patients with acute inflammatory conditions, including Covid-19 Ards”.
Mesoblast fell six cents or 2.7 percent to $2.17 with 6.5 million shares traded.

CYNATA THERAPEUTICS

Cynata says that a 14-sheep study shows that its stem cells reduce lung injury severity, inflammation and circulatory shock in acute respiratory distress syndrome.
Cynata said the independent study at Brisbane’s Prince Charles Hospital administered sheep either Cymerus mesenchymal stem cells (MSCs) or a placebo while undergoing extracorporeal membrane oxygenation (ECMO) and then monitored for 24 hours.
The company said the study showed that its stem cells reduced the severity of lung injury ($p = 0.04$) and reduced inflammation as shown by cytokine interleukin 8 (IL-8) levels at three, 13 and 23 hours ($p = 0.013, 0.016, 0.028$, respectively).
Cynata said that Cymerus reduced the depth and severity of circulatory shock.
The company said that the study showed that its stem cells adhered to membranes in the ECMO device and resulted in a significant increase in pressure and a higher incidence of thrombosis in the lungs post-mortem, which could potentially lead to failure of the ECMO device and the study team “concluded that they cannot currently recommend the use of MSCs in combination with ECMO” but did not have implications for Ards patients not receiving extracorporeal membrane oxygenation.
Cynata said a research article, titled ‘Combined Mesenchymal Stromal Cell Therapy and ECMO in ARDS: A Controlled Experimental Study in Sheep’, had been accepted for publication in the American Journal of Respiratory and Critical Care Medicine.
Cynata chief operating officer Dr Killian Kelly said the beneficial effects of Cymerus was encouraging and it was “very useful” to learn about practical mechanical challenges associated with administering MSCs, but “most patients with Ards do not receive ECMO”.
“In humans with Ards who are not receiving ECMO, we expect to be able to administer repeated intravenous infusions of MSCs, which may have advantages compared to the approach that was taken in this preclinical study,” Dr Kelly said.
Cynata was up eight cents or 10.6 percent to 83.5 cents.

KAZIA THERAPEUTICS

Kazia says its 24-patient, phase I study of Cantrixil for metastatic ovarian cancer resulted in one complete response and two partial responses.

Last year, Kazia said two of nine patients had a partial response, tumors “reduced in size by 30 percent or more” and median progression-free survival across all nine patients was 5.5 months compared to historical data of 3.4 months (BD: Sep 30, 2019).

Today, the company said preliminary analysis of 20 of 24 patients evaluable for efficacy showed one complete response and two partial responses for an overall response rate of 15 percent or three of 20 patients compared to 10 percent for historical controls.

Kazia said the safety profile was consistent, with most adverse events being low-grade and gastrointestinal in nature.

Kazia chief executive officer Dr James Garner said “the preliminary results are extremely encouraging”.

“For some patients in this very challenging patient population, Cantrixil has been able to shrink tumors and delay disease progression, demonstrating a clinically meaningful benefit,” Dr Garner said.

Australian lead investigator Prof Jermaine Coward said the phase I study was conducted in a very late-stage patient population, with few effective treatment options and “in that context my colleagues and I consider these data to be extremely promising”.

Kazia was up half a cent or 1.2 percent to 43.5 cents.

MICRO-X

Micro-X says it has raised $8.75 million through a placement and hopes to raise a further $6.25 million in a one-for-5.6, underwritten entitlement offer at 14 cents a share.

Micro-X said the issue price was at a 20 percent discount to the 17.5 cent last traded price on April 14, 2020.

The company said that under the entitlement offer, shareholders would be able to apply for an additional top up number of shares, up to 50 percent of their entitlement.

Micro-X said the entitlement offer record date would be April 22, the offer would open on April 24 and close on May 6, 2020.

The company said the funds would be used to accelerate its Nano x-ray device scale-up in response to Covid-19 demand, accelerate commercialization of its Rover high power generator, development of its mobile backscatter imager and for working capital.

Micro-X said Morgans Corporate and Bell Potter Securities were joint lead managers to the placement and Hawkesbury Partners was corporate advisor.

Micro-X fell one cent or 5.7 percent to 16.5 cents with 1.7 million shares traded.

SOMNOMED

Somnomed says it has raised $5.8 million in the retail component of its one-for-3.24 rights offer at 80 cents a share, taking the total raised to $15,480,000.

Last month, Somnomed said it hoped to raise $15.5 million through an institutional and retail rights offer at 80 cents a share and raised $9,680,000 through the institutional component (BD: Mar 25, 26, 2020).

Today, the company said that new shares not taken up by eligible retail shareholders would be allocated to the sub-underwriters.

Somnomed said Wilsons Corporate Finance was the sole lead manager, bookrunner and underwriter to the entitlement offer.

Somnomed was up 18.5 cents or 16.3 percent to $1.32.

LIVING CELL TECHNOLOGIES

Living Cell says the Covid-19 pandemic and New Zealand Level 4 restrictions have halted obesity and migraine projects with the University of Auckland.
Living Cell said that due to the closure of the University progress was “currently halted on these two projects which target treatments for obesity and migraine”.
The company said that no milestone payments would be made with the projects on hold.
Living Cell said that board and management would have a 25 percent salary and fees cut for three months from April 15 and it was negotiating a rent reduction, had eliminated international travel costs and was negotiating with suppliers to reduce costs.
The company said it had applied for the government business relief packages in both Australia and New Zealand and expects to receive these in due course.
Living Cell said it would have sufficient cash to last at least to the end of 2021.
Living Cell was unchanged at 1.3 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it plans to transition its genetic testing laboratory to a high-throughput Covid-19 testing laboratory, if required.
Genetic Technologies said it had begun work to identify laboratory workflows, instrument modification and compliance for biologics and contaminated materials handling.
The company said its laboratory was Australian National Association of Testing Authorities (NATA) and US Clinical Laboratory Improvement Amendments (CLIA) accredited for and it had applied to Medicare to secure a rebate for any tests conducted.
Genetic Technologies executive chairman Dr George Muchnicki said the company was “prepared to transition our laboratory for the purpose of fighting the Covid-19 pandemic subject to government and community needs”.
Genetic Technologies was up 0.3 cents or 60 percent to 0.8 cents with 125.8 million shares traded.

PHARMAUST, THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

Pharmaust says it will work with Melbourne’s Water and Eliza Hall Institute to test the effects of monepantel on Covid-19 infections.
Pharmaust said it had evaluated monepantel, originally developed as a worm drench for sheep, for cancer in human and dog trials and the “mechanism of action in cancer may also prove to be beneficial in the treatment of certain viral diseases”.
The company said WEHI researcher Prof Marc Pellegrini would conduct studies on both monepantel and monepantel sulfone.
Pharmaust said that it would own all intellectual property results and rights under the materials transfer agreement and pay WEHI a nominal fee for undertaking the studies.
Pharmaust chief scientific officer Dr Richard Mollard said, “the studies will commence shortly and WEHI aims to provide a preliminary data summary in May 2020”.
Pharmaust was up 1.8 cents or 22.5 percent to 9.8 cents with 7.3 million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara has requested a trading halt pending a “proposed capital raising, comprising an institutional placement and a share purchase plan”.
Trading will resume on April 21, 2020 or on an earlier announcement.
Volpara last traded at $1.45.

MEDLAB CLINICAL

Medlab has requested a trading halt pending an “extension of [its] Nanocelle platform to anti-malaria drugs as part of COVID-19 research”.
Trading will resume on April 21, 2020 or on an earlier announcement.
Medlab Clinical last traded up one cent or 4.8 percent to 22 cents.

LIFESPOT HEALTH

Lifespot says it has added a Fevertel fever application to its Bodytel diagnostic tests, which include Glucotel, Pressuretel and Weighttel.
Lifespot said Fevertel included a digital thermometer, connected via Bluetooth to the user’s smart phone application and acted as an online reporting tool, manual entry influenza symptom tracker and diary.
The company said it would enable users to better inform telehealth providers of their temperature and self-recorded symptom information.
Lifespot said it was evaluating the potential of Fevertel to be extended for fever tracking and symptom data by geography and for a closed loop hybrid of Fevertel for organisations to track individual temperature data.
The company said Fevertel was being prepared for Australian Therapeutic Goods Administration registration and software development was underway, on track for an Australian winter 2020 launch.
Lifespot fell 0.7 cents or 12.3 percent to five cents with three million shares traded.

MGC PHARMACEUTICALS

MGC says it has ethics approval for a 14-day, 50 patient phase II trial of its supplement Artemic, based on a formulation of artemisinin and curcumin.
MGC said the trial at Israel’s Nazareth Hospital was expected to begin in April 2020 and conclude in September, with results available in October 2020.
On Wednesday, the company said it had a deal with Swiss company Micelle Technology AG for a product targeting viral infections with inflammatory complications, based on Micelle’s Mycell delivery system technology, which delivered natural ingredients in higher concentrations to the cells and was used in the formulation of a “natural anti-infective based formulation” based on artemisinin (BD: Apr 15, 2020).
MGC previously said its March 19 trading halt, suspension and series of seven extensions for a Swiss joint venture had nothing to do with Covid-19 and that there was “presently no reasonable basis established for the product to treat or cure Covid-19 symptoms or that the product kills the Covid-19 virus” (BD: Apr 15, 2020).
Today, the company said its clinical advisory team had concluded that the established scientific data of artemisinin and curcumin properties provided a rationale to test Artemic in the treatment of Covid-19 patients.
MGC managing director Roby Zomer said “following [the company’s] recently announced agreement with Micelle, this approval to proceed immediately with a phase II clinical trial of Artemic is a major milestone”.
“This trial will evaluate the safety and efficacy of Artemic on patients diagnosed with Covid-19 and we look forward to updating the market with developments,” Mr Zomer said.
MGC was up 0.8 cents or 32 percent to 3.3 cents with 114.7 million shares traded.

OPTHEA

Regal Funds Management says it has reduced its substantial shareholding in Opthea from 34,346,537 shares (12.76%) to 31,579,466 shares (11.73%).
The Sydney-based Regal Funds said that between March 12 and April 9, 2020 it bought 2,541,523 shares for between $1.19 and $2.42 a share and between March 13 and April 14, it sold 5,308,594 shares for between $1.31 and $2.31 a share.
Opthea was up 13 cents or 5.6 percent to $2.44 with 875,111 shares traded.

IMPEDIMED

Allan Gray Australia says it has increased its substantial shareholding in Impedimed from 68,550,246 shares (13.41%) to 139,761,906 shares (18.28%).
The Sydney-based Allan Gray said that between February 11 and April 3, 2020 it bought and sold shares, increasing by 71,211,660 shares, with the single largest purchase 6,062,627 shares for $227,349 or 3.75 cents a share.
Earlier this month, Impedimed said it had raised $10 million in the institutional component of a hoped for $24.9 million entitlement offer, including a $10 million institutional component and $14.9 million retail component at 3.75 cents a share (BD: Apr 2, 3, 2020).
Impedimed was unchanged at four cents with 15.5 million shares traded.

IMPEDIMED

Paradice Investment Management says it has increased its substantial shareholding in Impedimed from 22,763,711 shares (6.060%) to 65,941,454 shares (8.626%).
The Sydney-based Paradice said that between November 15, 2017 and April 14, 2020 it bought 45,419,304 shares for $837,779 or an average of 1.84 cents a share a share and sold 2,241,561 shares for $922,323 or an average of 41.15 cents a share.