Biotech Daily

Friday June 26, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: LBT UP 11%; OPTISCAN DOWN 15%**

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*** ZUCERO: ZU545 'POTENT ACTIVITY' AGAINST COVID-19, IN-VITRO**

*** RESPIRI, EDINBURGH UNI PARTNER FOR DATA**

*** ELLEX $100m LUMIBIRD LASER, ULTRASOUND SALE FINALIZED**

*** LIFESPOT: 42% REMUNERATION REPORT 1st STRIKE**

*** COGSTATE APPOINTS JOHN GLUECK CO-CO SEC**

MARKET REPORT

The Australian stock market was up 1.49 percent on Friday June 26, 2020, with the ASX200 up 86.4 points to 5,904.1 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and two were untraded.

LBT was the best, up two cents or 11.1 percent to 20 cents, with 635,558 shares traded.

Ellex climbed 9.8 percent; Resonance improved 6.45 percent; Uscom was up five percent; Impedimed, Oncosil and Starpharma were up more than four percent; Prescient was up 3.7 percent; Mesoblast and Resonance rose more than two percent; Antisense, Clinuvel, Next Science and Orthocell were up more than one percent; with Cochlear, Cynata, Nanosonics and Paradigm up by less than one percent.

Yesterday's 5.1 percent best, Optiscan, led the falls, down 0.6 cents or 14.6 percent to 3.5 cents, with 73,478 shares traded.

Proteomics lost 8.1 percent; Alterity retreated 6.25 percent; Compumedics was down 5.6 percent; Actinogen, Avita and Universal Biosensors fell more than four percent; Opthea was down 3.1 percent; Genetic Signatures and Kazia shed more than two percent; Medical Developments, Polynovo and Volpara were down more than one percent; with CSL down 0.4 percent.

DR BOREHAM'S CRUCIBLE: RACE ONCOLOGY

By TIM BOREHAM

ASX code: RAC

Share price: 62 cents; **Market cap:** $72.2 million; **Shares on issue:** 116,450,037

Financials (March quarter 2020): receipts $15,000, cash outflows $666,000, cash on hand $2.56 million, number of quarters of available funding: four

Executive chairman: Dr John Cullity

Board: Dr Daniel Tillett (CSO, COO), Dr Cullity, Chris Ntoumenopoulos, Dr William Garner, Phillip Lynch, Prof Borje Andersson

Identifiable major shareholders: William James Garner 11.75%, Dr Daniel Tillett 7.90%, Merchant Opportunities Fund 6.15%, Dr Molloy 3.43%

Have you ever looked under the couch cushion and found a fortune in long-lost coins?

It sounds incredible but the same thing can happen with forgotten drugs - even ones that have been approved.

In the case of Race, the 'sofa cushion' moment came in 2013 when US physician and entrepreneur Dr William Garner reviewed medical literature about a cancer drug called bisantrene.

Bisantrene underwent 15 years of clinical trials and was even approved by French drug keepers in 1990, but a series of corporate takeovers consigned the drug to the back of the Chesterfield.

Race has revived efforts to commercialize bisantrene, not so much for re-purposing but for the drug's original remit of treating the difficult acute myeloid leukaemia (AML).

Despite the progress with alternative drugs in the ensuing decades, recent trial results shows the drug is promising for treating AML patients on their last legs.

The big trouble with the current drugs (anthracyclines) is that they can cause cardiomyopathy or, in executive chairman Dr Cullity's words: "a floppy bad heart".

Bisantrene was developed in the 1980s by French group Lederle Laboratories as a "next generation" version of an anthracycline.

By modifying the basic anthracycline molecule, the inventors aimed to maintain the same DNA binding effects but reduce the cardiotoxicity.

Give me a sense of (re)purpose

In the 1980s and 1990s, more than 40 clinical trials covering 2,000 patients confirmed both the lack of cardiotoxicity and the anti-tumor activity.

“We got efficacy (data) and a King Kong-sized file on safety, based on hundreds of patients,” Dr Cullity says.

Generally speaking, acute myeloid leukaemia is an aggressive cancer resulting in only 34 percent of patients surviving for more than a year. The odds reduce to 20 percent on the first relapse and eight percent on the second.

The trials (carried out mainly in France) showed a complete remission rate of 38 to 72 percent, or an average 48 percent across 85 patients.

(OK- one trial showed a mere five percent remission rate, but the wrong dosage was used.)

Gallic authorities approved the drug in 1990, but then a chain of takeovers meant that Lederle’s oncology division ended up with American Cyanamid.

One way or the other, interest waned and it was bye-byes time for bisantrene.

Race was formed in July 2016 to acquire bisantrene from the Nevada-incorporated Update Pharma, owned by Dr Garner, pharmaceutical scientist Dr John Rothman and Peter Molloy.

Dr Molloy is best known as head of the ASX-listed Biota, which developed the influenza drug Relenza before moving to the US.

Race listed in July 2016 via the shell of Coronado Resources, raising $4.3 million at 20 cents apiece.

The CEO since listing, Dr Molloy resigned in May to head up a company called Firebrick Pharma.

Since then the whole shebang has been run by Dr Cullity and Dr Daniel Tillett, the company’s CSO-cum-COO*****.

Dr Cullity’s career took him from his childhood playground of Cottosloe Beach in Perth to a University of Western Australia medical degree and then to the London School of Economics and Wharton Business School.

He also had stints at the World Health Organisation, the World Bank, and big pharma Sanofi before joining the New York biotech deal shop Torreya Partners.

Doctors Garner and Molloy one day dropped in for some corporate advice, which led to Dr Cullity eventually being invited to join the Race board.

***** chief scientific officer cum chief operating officer.

Clinical trials

Race shares went on a romp in mid-June after the company unveiled the results of a phase II trial for relapsed or refractory AML patients, carried out at Israel's Sheba Medical Centre.

The trial was open label, which means both the patient and the doctor knew the treatment they were receiving. A placebo control group was inappropriate.

The trial enrolled 10 patients aged between 22 and 80, who had failed at least three treatment options.

Seven of them had relapsed after receiving an allogeneic stem cell transplant (using tissue from someone else).

Four of them had tumors outside the bone marrow, known as extramedullary AML. Interestingly, these were the four who responded.

Of these patients, one achieved complete remission and three achieved partial remission: an overall clinical response of an "impressive" (the company's words) 40 percent.

This compares with "hospital experience" of a 20 to 30 percent response rate and is in line with the 20 to 50 percent response with the old trials. But four of 10 patients is a very small sample group.

Apart from lesser side effects such as mouth ulcers and low platelet counts, no major adverse events were recorded.

Dr Cullity says in such cases the response to the therapy is more crucial than the survival experience, because the multiple treatments muddy the picture.

"How do you unscramble the egg?" Dr Cullity asks. "The answer is you will never know what intervention was the key driver for survival because (the patients) have had the kitchen sink thrown at them."

Prof Borje Andersson, the chair of Race's clinical advisory board, says the patients were at high risk of not responding at all and the company would have been happy with a 10 percent response rate.

A global leukaemia and stem cell transplant expert based at MD Anderson Cancer Centre in Houston, Texas, Prof Andersson adds the side effects were similar to the results from three decades ago, using the same 250 milligram dose.

The primary endpoints of the trial were overall survival over 24 months, as well as leukaemia-free survival over the two years.

"While we must study the drug further, it appears that with this kind of response bisantrene-based therapy may have potential to serve as an important bridge to an allogeneic stem cell transplantation in patients who otherwise have few therapeutic options," he says.

What's next?

While there's been a lot of action with acute myeloid leukaemia therapies over the last decade, there are various treatment sub-sectors.

"You need to be wary about where the best value is," Dr Cullity says. "You want to drive around traffic, not into it."

With the dexterity of the Michael Schumacher of old, Race's management is now steering the company through a five-step program, including three further potential acute myeloid leukaemia trials. The company is talking to Sheba about running a phase II program for relapsed and/or refractory AML, but based on a combination therapy.

"I can't tell you the exact size but it will be much larger," Dr Cullity says.

In the US, the company is pondering a separate trial for paediatric AML patients who have received large - and possibly maximum - doses of cardiotoxic anthracyclines.

"It's a real tragedy when kids have induction therapy, move into durable remission and are transplanted, but then are left with an underperforming heart," Dr Cullity says.

"They can't kick a soccer ball or in the worst-case scenario they require a heart transplant."

This effort is being overseen by Dr Jaap Boelens, head of paediatric leukaemia at New York's Memorial Sloan Kettering Cancer Center.

Race is also considering a third trial to target the 25 percent of AML patients supposedly in remission with measurable residual diseases, or MRD.

MRD-positive patients have an approximate 20 percent chance of two-year survival, but with MRD-negative cases the odds improve to 80 percent (post bone marrow transplant).

Dr Tillett says an MRD therapy could allow the company to enter a market that's larger and less competitive than the broader market for 'salvage' acute myeloid leukaemia.

The fourth and fifth stages refer to proof-of-concept combination trials for the use of bisantrene for breast and ovarian cancer.

With two million new breast cancer and 200,000 new ovarian cancer cases a year, these are both bigger markets than AML.

Financials and performance

Race ended the March quarter with a cash kitty of $2.56 million, having burned the Devil's number of $666,000 during the stanza. The company also raised $1.69 million in a placement corner-stoned by the ubiquitous biotech investor Merchant Opportunities Fund.

Dr Cullity says the clinical results provide Race with solid grounds to pursue “sensible, titrated and balanced capital formation” - which to you and I means a likely capital raising.

Race is also eyeing a US Food and Drug Administration priority review voucher - a.k.a. a Willy Wonka golden ticket - for a paediatric therapy. These vouchers are fungible (transferable) and currently are being bought and sold on the secondary market for up to $100 million.

In June, the company settled the outstanding matter of a limited recourse loan granted to Dr Molloy when he joined.

The loan was by way of four million Race shares issued at a deemed 20 cents apiece and funded by an $800,000 loan. The loan became payable on Dr Molloy’s departure, and was settled via a buy-back (and cancellation) of 2.22 million shares with a deemed value of 36 cents apiece.

Shareholders will vote on the buy-back proposal at a general meeting to be held in late July or early August.

The June 16 results sent Race shares soaring 16.5 cents, or 52 percent to 48 cents and they have since further elevated to record levels. In July 2019, the stock plumbed a low of 4.5 cents, at which point your columnist backed up the truck and piled in … in his dreams.

Dr Boreham’s diagnosis:

Drug repurposing is a popular sub-sector of life sciences and need we mention Paradigm Biopharmaceuticals with its program to treat osteoarthritis with a very old blood-thinning drug?

The benefit of ‘rebirthing’ lies in the ability to leverage millions of dollars of past investment - $200 million in the case of bisantrene - which leads to a cheaper and faster route to approval.

Reviving a drug for essentially the same purpose - which Race is attempting - is less risky than re-inventing it for an entirely different indication.

“In short we have reset bisantrene; it was a long time between drinks,” Dr Cullity says. “We have now put it in a small yet precise phase II experiment and the drug is talking to us.”

If the drug ‘talks’ some more with the expanded trials, this company is indeed is off and Race-ing.

Just watch those chicanes along the way.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has not found a wonder drug behind his sofa cushion but did retrieve a dozen bottle tops and a long-lost remote control.

ZUCERO THERAPEUTICS

Zucero says in-vitro studies of ZU545, or pixatimod, has shown it has “potent antiviral activity” against Covid-19.

In March, Zucero said it would investigate the efficacy of its lead clinical candidate pixatimod, previously ZU545 and Progen’s PG545, against Covid-19, as it had shown anti-viral activity against several viruses, including respiratory syncytial virus, herpes simplex virus, HIV and Ross River fever, by blocking the binding of virus particles to the surface of a host cell (BD: Mar 25, 2020).

Today, the company said the in-vitro studies showed that pixatimod bonded directly to the severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) spike protein sigma-1 (S1) receptor binding domain (RBD) which altered the virus shape.

Zucero said that pixatimod was being tested as both an anti-viral and oncology therapeutic, with an ongoing 83-patient phase Ia/Ib oncology trial determining that it was safe in humans.

The company said the potency of pixatimod to have anti-viral effects was “well within the safe therapeutic dose range of pixatimod as previously recorded in oncology patients in phase I studies”.

Zucero chief scientific officer Dr Keith Dredge said that the “results highlight a new therapeutic approach to directly inhibit the Sars-Cov-2 virus and clearly support further testing of pixatimod for use in the treatment and prevention of Covid-19”.

The company said it was a recipient of Therapeutic Innovation Australia’s Pipeline Accelerator Covid-19 voucher-based scheme, to support the progress of pixatimod into clinical trials for Covid-19.

The Therapeutic Innovation Australia website said the accelerator was designed to respond quickly to the needs of researchers and industry related to Covid-19.

The research was published in an article, titled ‘Pixatimod (PG545), a clinical-stage heparan sulfate mimetic, is a potent inhibitor of the SARS-CoV-2 virus’ co-authored by Dr Dredge, at: https://www.biorxiv.org/content/10.1101/2020.06.24.169334v1.

Zucero is a public unlisted company

RESPIRI

Respiri says it will partner with the University of Edinburgh to collect data for respiratory conditions.

Respiri said the Breathe Health Data Research Hub was led by the University of Edinburgh’s Prof Aziz Sheikh and was one of seven hubs established by Health Data Research UK funded by the British Government.

The company said it would use data, such as that collected by its Wheezo asthma detector, to develop better treatments for asthma, chronic obstructive pulmonary disease and respiratory infections.

The company said it would work with Breathe to expand its program to the UK as it prepared to enter the European market in 2021, after its commercial launch in Australia expected by the end of this year.

Respiri chief executive officer Marjan Mikel said that “Wheezo brings cutting edge innovation in monitoring of respiratory disease and this is an incredible opportunity to demonstrate how the platform is beneficial to patients, the industry and the [UK National Health Service]”.

“The timing is perfect for Respiri as we now have [Conformité Européenne] mark, clearing Wheezo for our European commercial launch in 2021,” Mr Mikel said.

Respiri was up 0.4 cents or 4.65 percent to nine cents.

ELLEX MEDICAL LASERS

Ellex says it has satisfied all conditions for the sale of its laser and ultrasound business to Lumibird Group SA and will complete the transaction by June 30, 2020.
In December last year, Ellex said the Lannion, France-based Lumibird would pay $100 million in cash for its lasers and ultrasounds business (BD: Jan 19, 2020).
Earlier this month, the company said the sale had been cleared by the Australian Competition and Consumer Commission (BD: Jun 11, 2020).
Today, the company said the transaction was “unconditional”.
Ellex was up six cents or 9.8 percent to 67.5 cents.

LIFESPOT HEALTH

Lifespot says its annual general meeting passed all resolutions, but with 41.8 percent of votes earning a first strike against the remuneration report.
Lifespot said the remuneration report had 24,382,087 votes (41.8%) against, with 33,878,665 votes (58.2%), in favor, earning a ‘first strike’.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed the directors must stand for re-election.
The company said its resolution to issue up to 20,000,000 for a proposed placement was opposed by 27,528,654 votes (45.3%), with 33,202,104 votes (54.7%) in favor.
Lifespot’s most recent Appendix 2A new issue announcement said the company had 96,788,303 shares on issue, meaning that the votes against the issue of 20,000,000 shares amounted to 28.4 percent of the company, sufficient to requisition extraordinary general meetings.
The company said that the re-election of director Francecso Cannavo, the approval of a previous issue of 10,128,635 shares, the issue of placement shares to Rodney Hannington, and the additional of capacity to issue shares were passed with wider margins.
Lifespot was up 0.3 cents or 9.7 percent to 2.8 cents.

COGSTATE

Cogstate says it has appointed it general counsel John Glueck as company secretary, effective from today.
Cogstate said Mr Glueck had more than 20 years’ legal experience and, before joining the company in February as a member of the general counsel, was the chief compliance officer for Axogen Inc, and previously worked for Medtronic and Covidien.
The company said Mr Glueck held a Bachelor of Arts and a Juris Doctor degree from New York’s Fordham University.
Cogstate chief executive officer Brad O’Connor told Biotech Daily that company secretary Keith Hawkins who was appointed last year would continue as company secretary, with Mr Glueck appointed as “a second company secretary to help with the workload”.
Cogstate fell 1.5 cents or 4.3 percent to 33.5 cents.