Biotech Daily

Friday May 31, 2019

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: TELIX UP 7%; CYCLOPHARM DOWN 13%**

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*** TPI BACKS PALLA NAME CHANGE; 22% SUPPORT WITHDRAWN SPILL**

*** YUUWA DILUTED TO 39% OF ADALTA**

*** NANOSONICS LOSES 9-YEAR DIRECTOR RICHARD ENGLAND**

*** ADMEDUS LOSES 5-MONTH DIRECTOR LISHAN ZHANG**

MARKET REPORT

The Australian stock market edged up 0.08 percent on Friday May 31, 2019, with the ASX200 up 4.8 points to 6,396.9 points.

Nine of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and four were untraded. All three Big Caps were up.

Telix was the best, up 6.5 cents or 6.6 percent to $1.055 with 753,195 shares traded. Antisense and Nanosonics climbed four percent or more; Impedimed, Orthocell and Pharmaxis were up more than three percent; Clinuvel, Ellex and Genetic Signatures rose more the two percent; Cochlear and Resmed were up more than one percent; with CSL up 0.9 percent.

Cyclopharm led the falls, down 19 cents or 12.75 percent to $1.30, with 24,000 shares traded. LBT lost 10.8 percent; Proteomics fell 9.7 percent; Oncosil shed 8.7 percent; Medical Developments and Patrys were down more than six percent; Imugene retreated 5.6 percent; Avita and Osprey fell more than four percent; Pro Medicus was down 3.15 percent; Alterity (Prana), Kazia, Mesoblast and Prescient shed more than two percent; Neuren was down 1.5 percent; with Opthea and Paradigm down less than one percent.

DR BOREHAM'S CRUCIBLE: INVITROCUE

By TIM BOREHAM

ASX code: IVQ

Share price: 6.5 cents

Market cap: $34.1 million

Shares on issue: 525,325,685

Financials (March quarter*): receipts $128,000, cash burn $1.2 million, cash on hand $531,000, estimated current quarter outflows $1.03 million

***** Figures are in Singapore dollars. Currently $S1.00 equals $A1.05

Chairman and founder: Dr Boon Sing (Steven) Fang

Board: Dr Fang, Ee Ting Ng, Kit Wei Lui, Prof Hanry Yu, Dr Andreas Lindner, Dr Gary Pace

Identifiable major shareholders: Fang Boon Sing 22.03%, Prof Yu 9.44%, Icure Ltd 3.65%, Inbridge Ventures 3.42%, Anatoly Larionov 1.16%.

When it comes to the latest sideline of the Singaporean 'personalized oncology' outfit, we won't hear a squeak of dissent from investors.

In a tie-up with a leading scientist from Singapore's Agency for Science, Technology and Research (Astar), Invitrocue will supply "humanized" mice for clinical studies.

'Humanized mice' doesn't mean you can have a decent convo with them about the footy or politics. Rather, they have been imbued with either a stable and functional human immune system or an immune-deficiency.

Research house Markets and Markets estimates the humanized mouse market will be worth $US129 million by 2022 growing at 10 percent.

According to Invitrocue supremo Dr Steven Fang, these modified rodents are no common or garden vermin, and the sell for $US1000 apiece. "We make a good margin out of it, too," he says.

The venture will be 70 percent owned by Invitrocue and 30 percent by Dr Chen Qingfeng.

But let's not get too distracted by the rats and mice stuff as Invitrocue begins the commercial rollout of its core product its oncology (cancer) patient-derived organoids, or Onco-PDO, which tests oncology drugs for efficacy on a particular patient's tumors.

The test is currently being rolled out in China, the Philippines, Singapore, Thailand, Malaysia, Vietnam, Indonesia, Germany, Spain, the UK and Austria.

Oh, and let's not forget Australia and New Zealand.

The core premise behind Onco-PDO is that cancer drugs on average work 35 percent of the time - and in some cases only five percent of the time.

"Doctors might be happy with 35 percent but if you ask a patient it's not good betting odds," Dr Fang says.

Indeed.

Invitrocue's underlying philosophy is that while everyone has a unique genetic makeup, there's a 'one size fits all' approach applied to standard drugs.

Some of these remedies have a miserable success rate, but can be more effective with particular patients.

Invitrocue's evolution

Assisted by a joint research grant from the Massachusetts Institute of Technology, Invitrocue was spun out of Astar (the Singaporean equivalent of the CSIRO).

The company back-door listed on the ASX in January 2016, raising $3.15 million.

The company licenced its core know-how at an "attractive rate" from inventor and Invitrocue co-founder Prof Henry Yu.

"We are benefiting from about $40 million of investment so far," Dr Fang says.

Initially, the company focused on testing liver cells and provided services to the big pharmaceutical companies.

The founders then realized that oncology testing would be more exciting than providing liver testing services to the drug companies.

Dr Fang says cancer might be one the most common afflictions but it is also one of the most complex diseases to treat.

"There's no magic bullet where one cancer drug or a cocktail of drugs can kill off these sub-classes of cancer cells," Dr Fang says.

The trouble is, we don't know enough about what drugs work and what ones don't.

Testing times

Invitrocue's Onco-PDO test derives from 'oncology patient derived organoid'.

Yeah, we knew that.

The test is based on a portion of tissue removed during surgery or routine biopsy and then treated with the proposed cancer drugs.

Grown on scaffolds using a 3D culture, the cells in effect are an 'avatar' of the original tumor.

The test takes three days and on average assays 10 to 15 drugs from a panel of 80 therapies. Within two weeks, the oncologist receives the report.

An important legal distinction is that Invitrocue does not recommend a drug per se.

"Our role stops where the doctor's role starts," Dr Fang says. "We do not advise on the best drugs. We simply lay out what drug kills what percent of the cancer cells and that's it. The doctor needs to decide what to do with the information."

Dr Fang says the test can ascertain with 100 percent reliability that a drug won't work, while being 96 percent a drug does work.

The 100 percent negative assurance is possible because the drug is tested at such a large dosage it would kill a patient if administered in-vivo.

Currently, the test can be used to assess treatments for head, neck and shoulder cancer, as well as breast, lung and colorectal cancers.

Under a recently formed alliance with the Shanghai Institute of Biochemistry and Cell Biology, Onco-PDO is relevant for 10 breast cancer types including oestrogen receptor positive (ER+), progesterone receptor positive (PR+), human epidermal growth factor receptor 2 positive (HER2+) and triple negative breast cancer (TNBC).

Next year the test should also be available for ovarian and prostate cancers, as well as neuroblastoma (brain cancer) and leukaemia.

Finances and performance

Invitrocue generated $S124,089 of revenue in the December 2018 half-year and also doubled its loss to $S3.5 million. The March quarter showed receipts of a modest $S128,000 and a $S1.2 million loss.

But with Onco-PDO sales only just beginning, these proceeds were from the old liver cancer test.

Unusually, Invitrocue sells the test for a flat 3,000 - as in 3,000 Euros for Germany, $S3,000 for Singapore and Asia and, of course 3,000 Aussie dollars here.

In reality, the end patient price is between $S4000 and $S6000, with the hospitals marking up the price to cover their costs.

“We don’t share revenue with them and we get to keep all our margins, which are hovering around 60 to 70 percent,” Dr Fang says.

The company cites a current addressable market of 2.7 million “incidents” across Asia, Europe, Australia and New Zealand.

Under Invitrocue’s ‘capital light’ model, the company does not own the laboratories where the tests are carried out, but rents space and facilities from other parties.

Currently, the company avails facilities in Singapore, Shanghai and Munich.

With Invitrocue’s cash balance down to half a million or so by the end of the March quarter, we would expect the company to tap the market for more funds.

Since listing, the sparsely-traded Invitrocue shares have been as low as 5.5 cents (July 2016 and April 2019) and as high as 11 cents (March 2016 and March and July 2018).

Dr Boreham’s diagnosis:

There’s no question of demand for Onco-PDO at a macro level, with 15 million new cancer cases a year and this number is expected to double by 2040.

While there’s a US start-up and a Dutch hospital dabbling in the onco-drug testing game, Invitrocue appears to have the territory to itself.

A key selling point for Onco-PDO is the test’s ability to test for 10 different types of breast cancer.

“Any company that can provide information to help doctors decide the right drug for the right patient at the right time is going to be a huge market,” Dr Fang says.

Of course, Invitrocue needs to prove it can capture a meaningful share of this market.

If it can’t, there’s always the mice to fall back on but you need to catch the buggers first.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. As a kid he had pet mice and then a pet cat, after which he no longer had pet mice

AUSBIOTECH

Ausbiotech says its annual survey shows “a worrying fall in business sentiment across the sector led by uncertainty over the [Research and Development] Tax Incentive”.

Ausbiotech said the survey, supported by accountancy firm Grant Thornton, had responses from 43 chief executive officers and showed that while there was strength in the life sciences growth trajectory, business sentiment was negative due to “the steady erosion of government support”.

The industry organization said that 14 percent of respondents, or six CEOs, described the Australian operating environment as “conducive to growing a biotech business”, down from 37 percent in the previous survey.

Ausbiotech said the results were “the worst … this decade” suggesting a “challenging” period ahead, with 26 percent of respondents believing the environment “works against growing a biotech business”, up from 16 percent in the previous corresponding period.

Ausbiotech chief executive officer Lorraine Chiroiu said the “industry is frustrated at the Government’s lack of commitment to a business environment that better supports our cutting-edge research and development, however, Australia’s strength in life sciences still shines globally and contributes nationally [both] economically and socially”.

Grant Thornton life sciences head Michael Cunningham said “we need greater support to the commercialization process to keep the profits and future development opportunities from the life sciences sector here in Australia”.

“Emerging markets in the Asia-Pacific region are making biotechnology a priority, and Australia must continue to provide an attractive landscape for life sciences firms to conduct [research and development], manufacturing and domestic distribution activities to fuel growth in 2019 and beyond,” Mr Cunningham said.

Ausbiotech said there was a strong view that, as research left public institutions for commercialization, support for technology transfer and commercialization diminished.

The survey said that ineffective policy decisions were a result of poor metrics and a lack of understanding of the skills and investment needed for biotechnology’s future.

Ausbiotech said Australia was preparing for a “regenerative medicine revolution” which would disrupt the health treatments available to patients world-wide.

The survey said that the sentiment to medicinal marijuana was shifting and Australian companies were demonstrating “the medicinal value for patients”.

The survey is available at: https://bit.ly/2KecGC3.

ALTHEA GROUP

Althea says it has launched its Concierge marijuana prescription platform in the UK

Althea said its Concierge UK would streamline the prescription process and facilitate patient referrals from primary care doctors to Althea UK specialist prescribers.

The company said it had partnerships with scientific committees Drug Science and the Improving Outcomes in the Treatment of Opioid Dependence (IOTOD).

Althea said that joint educational meetings with Drug Science planned for June 2019 were oversubscribed, with about 300 healthcare professionals registered to attend.

The company said Drug Science was the UK’s “only completely independent scientific committee on drugs” and was headed by neuro-psycho-pharmacologist and former senior advisor to the UK government Prof David Nutt.

Althea chief executive officer Josh Fegan said that “the launch of Althea Concierge UK and progression of our partnerships with [Drug Science and IOTOD were] key developments for our UK expansion”.

Althea fell 3.5 cents or 4.7 percent to 70.5 cents.

TELIX PHARMACEUTICALS

Telix says Emory University will conduct a 140-patient phase II trial comparing TLX591-CDx against fluciclovine for post-operative prostate cancer imaging.

Telix said the US National Institutes of Health awarded researchers at the Atlanta, Georgia-based Emory University Winship Cancer Institute a $US3.4 million ($A4.9 million) grant to compare TLX591-CDx or 68-gallium prostate membrane specific antigen (68GA-PSMA), marketed as Illumet, against fluciclovine marketed as Axumin.

The company said the prospective, randomized study had application for "advanced prostate imaging techniques to guide radiotherapy".

Emory radiologist Dr David Schuster said the University had worked "very closely" with Telix to begin the study with the Illumet kit, including referencing the company's US Food and Drug Administration drug master file in its investigational new drug application.

"The ease of use of the Telix product has made nuclear pharmacy validation straightforward and we are pleased to be collaborating with the company to complete this study," Dr Schuster said. "This trial involves many innovative components including the first use of PSMA [positron emission tomography] in Georgia and continues Emory's tradition of innovation including the development and first use of fluciclovine for prostate cancer imaging."

Telix chief executive officer Dr Christian Behrenbruch said the study was "a robust, prospective evaluation of how advanced prostate imaging has the potential to impact the application of radiotherapy techniques".

Separately, Telix told the ASX that the Emory collaboration media release was filed to the ASX after it had been published in the US due to a miscommunication with the US Global Newswire publishing company.

The company said that Global Newswire was meant to release the announcement after 9am Australian Eastern Standard Time (AEST) but misunderstood the direction and released it after 9am US Eastern Standard Time (EST).

The ASX said that Listing Rule 15.7 says: "An entity must not release information that is for release to the market to any person until it has given the information to [the] ASX and has received an acknowledgement that [the] ASX has released information to the market".

The ASX said a listed entity must not release information "to any person, including the media, even on an embargoed basis, until it has given the information to ASX and received an acknowledgement that ASX has released it to the market".

"As the article has appeared in Dow Jones Institutional News prior to the Announcement being released to ASX, it appears that [Telix] may have breached listing rules 3.1 and/or 15.7," the ASX said.

Telix said that previously it had sent its announcements to Global Newswire to be released after they had been released to the ASX and would "revise its process so that its releases no longer be queued but will rather be lodged live subsequent to receipt from the [ASX] that the announcement has been released to market".

Telix was up 6.5 cents or 6.6 percent to $1.055.

ADMEDUS, BTC HEALTH

BTC says it has completed its $6.3 million acquisition of the Admedus hospital infusion business.

Earlier this month, BTC said it would raise $8 million at 8.0 cents a share to buy the business through its subsidiary BTC Speciality Health Pty Ltd (BD: May 13, 2019).

BTC was fell half a cent or 4.55 percent to 10.5 cents.

Admedus was in an extended suspension and last traded at six cents.

IMAGION BIOSYSTEMS

Imagion's annual general meeting passed all resolutions but with 22.1 percent opposition to the 10 percent placement facility.
Imagion said the placement facility had 44,119,088 votes (22.11%) against the resolution with 155,457,046 votes (77.89%) in favor.
The company said that all other resolutions passed easily, including the remuneration report, the election of directors Dr John Hazle and Mark Van Asten and the ratification of the prior issue of options.
According to Imagion's most recent Appendix 3B new issue announcement, Imagion had 322,742,824 shares on offer, meaning the votes against the placement facility was 13.7 percent of the company, sufficient to requisition extraordinary general meetings.
Imagion was unchanged at 2.5 cents.

TPI (TASMANIAN POPPY INDUSTRIES) ENTERPRISES

TPI says shareholders approved the name change to Palla Pharma, overwhelmingly passed the remuneration report, but 21.6 percent backed a withdrawn spill resolution.
Last year, TPI earned a remuneration report first strike with shareholders voting 25.44 percent against the report (BD: Jun 1, 2018).
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 reelection at a meeting within 90 days.
If the spill vote fails, the trigger is reset to no opposition.
Last night, TPI said the remuneration report was supported by 42,321,568 votes (99.77%) and opposed by 99,035 votes (0.23%), with the (later withdrawn) spill resolution opposed by 31,923,159 proxy votes (78.4%) with 8,816,670 proxy votes (21.6%) in favor.
According to the TPI's most recent annual report the company has 81,085,594 shares on offer, meaning the votes in favor of the withdrawn conditional spill resolution amounted to 10.9 percent of the company, sufficient to call extraordinary general meetings.
The company did not say when it the name change would take effect, nor its expected ASX trading code.
TPI was up half a cent or 0.4 percent to $1.18.

ADALTA

Yuuwa Capital says its 54,059,848 Adalta share-holding has been diluted from 46.81 percent to 39.40 percent following the $5 million placement (BD: May 23, 2019).
The Perth-based Yuuwa Capital's director Elizabeth McCall is a director of Adalta.
Adalta was up half a cent or 2.8 percent to 18.5 cents.

NANOSONICS

Nanosonics says that non-executive director Richard England will retire after nine years with the company.
Nanosonics said that Mr England joined the company in February 2010 and would remain on the board until the end of June to ensure a smooth close to the financial year.
The company said the board was "in advanced stages of recruiting another non-executive director" to replace Mr England.
Nanosonics was up 19 cents or 4.4 percent to $4.50 with 1.3 million shares traded.

ADMEDUS

Admedus says that non-executive director Lishan Zhang has resigned, effective immediately.

Admedus said Ms Zhang had been appointed in December 2018 and represented major investor Start Bright Holding (BD: Dec 12, 2018).