Biotech Daily

Friday June 23, 2017

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.17 percent on Friday June 23, 2017 with the ASX200 up 9.9 points to 5,715.9 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, nine traded unchanged and three were untraded.

Compumedics was the best for the second day in a row, up 6.5 cents or 10.3 percent to 69.5 cents with 1.1 million shares traded (BD: Jun 20, 2017).

Neuren climbed 10 percent; Viralytics was up 8.7 percent; Polynovo improved 7.7 percent; Orthocell was up 6.15 percent; Uscom climbed 5.3 percent; Atcor, Pharmaxis and Starpharma were up more than four percent; Mesoblast and Sirtex were up more than three percent; Acrux, Impedimed, ITL and Opthea rose two percent or more; Cochlear and CSL were up more than one percent; with Medical Developments and Nanosonics up by less than one percent.

Benitec led the falls, down one cent or 7.1 percent to 13 cents with 49,850 shares traded.

Osprey lost seven percent; Actinogen fell 4.8 percent; Ellex and Prima were down more than three percent; Bionomics and LBT shed two percent or more; Oncosil was down 1.1 percent; with Airxpanders, Factor Therapeutics, Pro Medicus and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: ADALTA

By TIM BOREHAM

ASX Code: 1AD

Market cap: $27.3 million; **Share price:** 27 cents; **Shares on issue:** 101.1 million (24.1 million in escrow)

Chief executive officer: Samantha Cobb

Board: Dr Paul MacLeman (chairman), Samantha Cobb, Dr Robert Peach, Dr John Chiplin, Libby McCall and Dr James Williams (Yuuwa reps)

Financials (March quarter): nil revenue, cash used $1.3 million ($2.45 million year to date), cash on hand $7.45 million, expected current quarter outflows $3.18 million

Major shareholders: Yuuwa Capital 53%, Platinum Asset Management 7.9%, Citycastle (Leon Serry) 5.2%, La Trobe University 3%, Robin Beaumont 1.87%.

Dr Crucible's maiden (and most likely only) award for PR Services to Piscatorial Predators of the High Seas goes to Adalta, an early-stage play focused on fibrotic conditions which are present in up to half of all human ailments.

That's because Adalta initially derived its crucial proteins, called i-bodies, from sharks (presumably deceased). So rather than being maligned for consuming hapless swimmers, sharks can be credited for advancing treatments for a range of human conditions.

Sadly though, we don't see Steven Spielberg clamouring for the film rights to Jaws: Vital Source Of Proteins That Mimic The Shape and Stability of a Crucial Antigen Binding Domain.

The Melbourne-based Adalta's focus is on lead candidate AD-114 to tackle idiopathic pulmonary fibrosis, a difficult to treat lung disease. While fibre is desirous in the content of wheat germ or Sultana Bran, fibrosis certainly is not. In essence, it's a scarring of tissues that can cause complete failure of vital organs.

Other targets are the eye disease wet aged-related macular degeneration (wet AMD), non-alcoholic steatohepatitis (NASH, or fatty liver disease), liver cirrhosis, the skin disorder scleroderma and cardiac fibrosis.

Adalta listed in August last year, raising $10 million at 25 cents apiece.

Other drugs 'don't work'

According to Adalta chief executive officer Sam Cobb, the current treatments - Boehringer Ingelheim's nintedanib and Roche's pirfenidone - have limited efficacy.

While these drugs represent a $US800-900 million a year global market, only 90 percent of patients respond.

“The side effects are so great that 70 percent of people will pull out and not use them,” Ms Cobb says.

To date, Adalta’s work has been confined to in-vitro (test tube) and in-vivo (mice) studies. These efforts to date have detected both anti fibrotic and anti-inflammatory activities in the lung - enough for the US Food and Drug Administration to grant an orphan drug indication.

The molecule has also proved effective against NASH and wet AMD in mice.

For the scientifically minded, Adalta’s I-bodies are derived from the I-set family of molecules which is one of four groups - the intermediate group - of immunoglobulin or immunoglobulin-like domains and are about one-tenth the size of normal human antibodies.

Adalta describes them as “long loops that can bind to a diverse range of therapeutically relevant targets including those that are difficult for current antibody therapies”.

Idiopathic pulmonary fibrosis (IPF) afflicts 300,000 folk globally - a relatively small number - and half will die within two to three years. The key benefits of orphan drug status are enhanced research and development credit, assistance with clinical trials, waived fees on an eventual new drug application (normally $US2 million) and seven-year marketing exclusivity.

The drug program was spun out of work at La Trobe Uni and the Commonwealth Scientific and Industrial Research Organisation, with $11m invested over the nine years preceding the initial public offer.

Big deals abound

Should investors get excited about such an early stage play?

“Yes” says Ms Cobb (although we guess she was never going to say “no”).

One reason is that there have been a number of big-ticket deals in the sector.

“Fibrosis is a hot topic with a lot of deals happening,” she says.

In September last year, Roche bought Adheron Therapeutics (another early stage IPF play) for $US105 million up-front plus $US475 million in milestones.

A month earlier, Promedior was acquired by BMS for $US150 million up-front and $US1.25 billion of potential milestones.

While the IPF market is small, the market for NASH alone is expected to be worth $1.6 billion by 2020. The wet AMD market is currently valued at $US8 billion, yet 30 percent of patients don’t respond and half of them go blind within three years, anyway.

What's next?

The company says it is fully funded for phase I development and next year hopes to secure a partnership "based on other benchmark deals".

Kerching!

In the meantime it's a case of the boring but important stuff such as toxicity studies and presenting and strengthening data (in the case of wet AMD, the National Health and Medical Research Council is chipping in).

"We have met all of our milestones," Ms Cobb says of progress to date.

Although, in October last year, the US Food and Drug Administration unexpectedly requested further information for the orphan drug application for AD-114 for idiopathic pulmonary fibrosis – effectively another mouse trial – but the designation was approved on-target in January this year.

Dr Boreham's diagnosis:

Since listing, the shares have traded between 16.5 and 31 cents.

Adalta is unusually well-backed for an early-stage developer, with the Perth-based biotech specialist Yuuwa Capital holding just over half the stock. Platinum Asset Management doesn't just go along for a speculative ride, while Circadian Technologies founder Mr Serry has official status as biotech doyen.

Board member Dr Chiplin was head of Arana Therapeutics, sold to Cephalon (now Teva) for a heady $US200 million. He also headed Domantis, which was in a similar field to Adalta and was sold to Glaxosmithkline for a handy 230 million English quids.

Fellow director Dr Paul MacLeman is a biotech old hand as former chief executive officer of Genetic Technologies and current chief executive officer of generic drug house IDT Australia.

And Dr Robert Peach was founder and chief executive officer of Receptos Inc, sold to Celgene Corp for $US7.8 billion in 2015.

Given the collective scientific and commercial nous, we deem Adalta as eminently punt-worthy.

As always, though, swim between the flags.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His only interaction with sharks is via investment bankers and a lightly battered flake accompanied by high-fibre chips.

CSL

CSL says the US Food and Drug Administration has approved Haegarda for routine prophylaxis to prevent hereditary angioedema in adolescent and adult patients.
CSL said that sub-cutaneous Haegarda, or human C1 esterase inhibitor was the only subcutaneous therapy indicated for hereditary angioedema (HAE), a rare, genetic and life-threatening condition that causes painful, debilitating and unpredictable episodes of swelling on the body, including the abdomen, face, larynx, and extremities.
The company said Haegarda was intended to be self-administered twice weekly.
CSL chief scientific officer and research and development director Dr Andrew Cuthbertson said that the FDA approval was “an important milestone for the HAE community because it addresses the primary need of patients to effectively prevent debilitating HAE attacks”.
“CSL Behring has a long heritage in HAE and thanks to our clinical trial participants, we’re proud to lead the community into the next era of treatment by offering the first and only subcutaneous preventive treatment option,” Dr Cuthbertson said.
The company said that hereditary angioedema was caused by deficient or dysfunctional C1-INH, a protein in the blood that helps to control inflammation and Haegarda targetted the root cause of HAE by replacing deficient or dysfunctional natural C1-INH, restoring functional C1-INH levels to above 40 percent of normal levels, reducing the risk of attacks.
CSL was up $2.33 or 1.65 percent to $143.33 with 825,121 shares traded.

LBT INNOVATIONS

LBT says it has completed the self-certification process for Conformité Européenne (CE) mark for its automated plate assessment system (APAS).
LBT said that with its joint venture company Clever Culture Systems AG it had completed a review of the documentation and data packs related to the APAS technology and certified that the requirements for CE mark had been met.
The company said that under the European Union certification system APAS was an unclassified, self-declarable in-vitro diagnostic medical device and could be CE marked by the manufacturer once a signed declaration of conformity was completed, stating the necessary safety and performance evidence had been met, to support compliance with European regulatory requirements.
LBT said that some countries, such as the UK and Germany, required a country-specific registration, which was a paperwork process undertaken closer to market launch.
Last year, LBT said the FDA had approved the APAS system for the automated imaging, image analysis, interpretation and reporting of growth on microbiology culture plates after incubation (BD: Oct 10, 2016).
LBT chief executive officer Brent Barnes said the process “required our internal engineering and quality teams to work closely with our regulatory consultants to complete a thorough checklist to ensure all requirements were met”.
“We are satisfied that given the exhaustive and rigorous testing and data including a 10,000 patient international clinical trial which supported the FDA clearance, we meet the requirements for CE mark certification,” Mr Barnes said.
“It’s an important milestone to achieve as we look to firm up distribution partners in the European region and gives potential distributors confidence in our ability to deliver a product in their markets,” Mr Barnes said.
“Completing this process means that we have de-risked our regulatory path to market in all key global markets, North America, Europe and Australia and New Zealand,” Mr Barnes said.
LBT fell half a cent or two percent to 24.5 cents.

BIOTRON

Biotron says it has raised $1,569,199 in an “oversubscribed” partly-underwritten renounceable one-for-four rights issue at two cents a share.
Biotron said that two cents was a 39 percent discount to the one month volume-weighted average price and each new share would come with an attaching option exercisable at six cents by November 30, 2018.
The company said that the rights offer was underwritten to $1 million by CPS Capital Group Pty Ltd which was also the lead manager.
In May, Biotron said that the funds would be used to complete complementary non-clinical assays on samples from its phase II HIV-1 clinical trial, evaluation of compounds against viral diseases including respiratory viruses, Dengue virus and hepatitis B, commercialization and negotiation activities, legal fees, travel, personnel costs and general working capital (BD: May 25, 2017).
Biotron was up 0.2 cents or 10 percent to 2.2 cents with 1.25 million shares traded.

CRYOSITE

Cryosite says it will sell its original core business of collection and processing of cord blood and tissue to Cell Care Australia for $500,000 plus $500,000 a year.
Cryosite said it would focus on its clinical trials logistics and biorepository services.
The company said that it had a binding agreement, subject to shareholder approval, to licence the collection, processing and storage of umbilical cord blood and tissue and sell some of its cord blood and tissue banking assets to Cell Care which held 19.7 percent of Cryosite.
Cryosite said there would be no change to its commitment to long term secure storage for its existing cord blood and tissue banking customers.
The company said the payment consisted of $500,000 in cash with earn-out payments over five years with a minimum fixed and guaranteed payment of $500,000 a year.
Cryosite said that additional earn-out payments would be conditional on the achievement of performance targets, along with the surrender through a buyback and cancellation of 9.23 million shares (19.7%) owned by Cell Care.
The company said a shareholder meeting was expected in September 2017.
Cryosite chairman Stephen Roberts said that “although Cryosite has a long involvement with cord blood and tissue banking, the demand for [its] collection and processing services has declined and this segment of our business has experienced downward pressure on profitability”.
“This transaction delivers attractive financial returns to Cryosite shareholders for exiting the challenging aspects of the cord blood and tissue business while retaining exposure to valuable future cash flows from royalties and earn-out payments,” Mr Roberts said.
“Moreover the transaction will support the deployment of additional capital into our higher margin clinical trials logistics and biorepository services which have established themselves over many years as high quality, customised and cost effective providers for clients,” Mr Roberts said.
“We see significant opportunities to build on Cryosite’s expertise in long term cold, frozen and cryogenic storage, logistics and distribution through acquisitions and organic growth initiatives,” Mr Roberts said.
Cryosite was unchanged at 16 cents.

INNATE IMMUNOTHERAPEUTICS

Innate has requested a trading halt pending “results from its phase IIb trial of MIS416 in patients with secondary progressive multiple sclerosis”.
Innate said it had received the results.
Trading will resume on June 27, 2017 or on an earlier announcement.
Innate last traded up half a cent or 0.8 percent to 64 cents.

NUHEARA

Nuheara says it has appointed Maxiim as a UK distributor and Dixons as a retailer for its Iqbud sound filtering and device ear buds.
Nuheara chief executive officer Justin Miller said the company had “cleared” more than 6,000 Iqbud pre-orders in April and begun retail initiatives in North America in May.
“Iqbuds are receiving great reviews and are now being stocked, distributed and sold by major consumer electronic organisations globally,” Mr Miller said.
Nuheara said that Maxiim was “a leading UK distributor of diversified consumer electronics” through supermarkets and catalogs as well as discount and specialty stores, while Dixons Carphone was an electrical and telecommunications retailer and services company.
Nuheara was up 0.2 cents or 2.6 percent to 7.9 cents with 8.2 million shares traded.