

Biotech Daily

Friday May 4, 2018

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: UNIVERSAL BIOSENSORS UP 11%; REVA DOWN 9%
- * DR BOREHAM'S CRUCIBLE: INNATE IMMUNOTHERAPEUTICS
- * CHINA'S CDH BIDS \$1.9b FOR SIRTEX; CLASS ACTION; ASX200
- * NANOSONICS RECEIVES CANADIAN CLEARANCE FOR TROPHON 2
- * RESONANCE DIABETIC RETINOPATHY FOR DEVELOPING COUNTRIES
- * ACORN BELOW 5% OF FACTOR THERAPEUTICS
- * HYDROPONICS NEW MARIJUANA GROWING SITE, SUPPLY AGREEMENTS
- * MMJ: HARVEST ONE BUYS DREAM WATER FOR \$36m CASH, SCRIP
- * QUEENSLAND BAUXITE TAKES MARIJUANA DEAL HALT TO SUSPENSION

MARKET REPORT

The Australian stock market fell 0.58 percent on Friday May 4, 2018 with the ASX200 down 35.4 points to 6,062.9 points. Twelve of the Biotech Daily Top 40 stocks were up,18 fell, eight traded unchanged and two were untraded.

Universal Biosensors was the best, up 2.5 cents or 11.4 percent to 24.5 cents with 201,585 shares traded.

Osprey climbed 10.3 percent; Oncosil rose 7.1 percent; Prana was up 6.7 percent; Prescient and Sirtex were up five percent or more; Starpharma improved 4.5 percent; Genetic Signatures was up 3.1 percent; Admedus, Nanosonics and Pro Medicus rose more than one percent; with Medical Developments and Resmed up by less than one percent.

Reva led the falls, down three cents or 9.1 percent to 30 cents with 131,313 shares traded.

Airxpanders and LBT lost more than seven percent; Volpara was down 6.4 percent; Benitec fell 5.7 percent; Avita and Telix were down more than three percent; Bionomics, Impedimed and Optiscan shed more than two percent; Cochlear, Cyclopharm, Cynata, Ellex, ITL, Opthea and Polynovo were down one percent or more; with Clinuvel, CSL and Neuren down by less than one percent.

DR BOREHAM'S CRUCIBLE: INNATE IMMUNOTHERAPEUTICS

By TIM BOREHAM

ASX code: IIL

Share price: 31 cents

Market cap: \$12.7 million

Shares on issue: 41,022,907*

Chairman and chief executive officer: Simon Wilkinson

Board: Simon Wilkinson, Dr Robert Peach, Andrew Cooke (company secretary), Dr Chris Behrenbruch, Dr Warwick Tong, Dr Christopher Burns

Departing directors: chairman Michael Quinn, Andrew Sneddon, Elizabeth Hopkins and Chris Collins

Financials (March quarter 2018): revenue nil, cash burn \$550,000, cash balance \$2.2 million, expected June quarter cash burn \$347,000

* After 10-to-one consolidation of existing 225 million shares on issue and issue of shares to Amplia.

Welcome back – we never expected to see you around these parts again!

The Auckland-based Innate looked a goner after its proposed multiple sclerosis treatment MIS416 spectacularly failed a phase II trial a year ago.

Now, Innate has emerged as an oncology-focused house with the rights to two pre-clinical immunotherapy assets. In fact, all the changes are expected to be finalized today, Friday May 4, showing how prescient or serendipitous this column can be.

At an extraordinary meeting on April 26, Innate holders waved through the company's proposal to purchase Amplia Therapeutics.

Amplia is a private Melbourne outfit that has the rights to two potential drug candidates targeting focal adhesion kinase (FAK) inhibitors.

Amplia is owned by parties including biotech man-about-town Dr Chris Behrenbruch, scientist Dr Chris Burns and Peter MacCallum Cancer Centre researcher Mark Devlin.

After MIS416 flopped, Innate had nowhere to go - and management admitted that in a rare outbreak of candor for the sector.

Rather than slicing and dicing the trial data to contrive a better result, the board swiftly curtailed activity to preserve funds and went in search of another pursuit.

Given MIS416 is a micro-particle targeting the regulatory and defensive functions of the immune system, the acorn hasn't fallen too far from the tree.

In fact, Innate was doing preclinical work on immune-oncology between 2004 and 2008 - well before it became sexy with investors and big pharma.

"If anything, the tree has moved close to the acorn," says Innate chief executive officer Simon Wilkinson.

Amplia in a nutshell

The Amplia deal sees Amplia holders emerge with 45 percent of the new Innate, or 18.5 million new shares.

The existing 225 million shares were consolidated to 22.5 million shares.

Amplia has licenced the assets from Cancer Research UK, with a patent life to 2033.

The program was initiated by the Melbourne based, Federal Government-funded Cancer Therapeutic Cooperative Research Centre.

Cancer Research UK is entitled to milestone and royalty payments, which Innate expects will not exceed \$200,000 over the next two years.

Mr Wilkinson says the company kissed between 15 and 20 frogs before settling on Amplia from a short list of three to five serious prince candidates.

"Some of the frogs we batted away after one phone call and some were looking to backdoor list new technologies that had nothing to do with biotech," Mr Wilkinson says.

Trump man remains supportive

The new board sees Mr Wilkinson continue as both chief executive officer and chairman. Dr Robert Peach, who led the due diligence on the acquired assets also remains.

Dr Behrenbruch, Dr Burns and Dr Tong and Mr Cooke join the board as Amplia reps.

A notable board departee is Chris Collins, US President Donald Trump's congressional liaison who held 17 percent of the old Innate and heavily spruiked the multiple sclerosis program in country club Republican circles.

Dr Tom Price, Mr Trump's pick as US Health Secretary, also received a private placement in the stock.

Innate-gate raised more than few eyebrows around Capitol Hill, to say the least, but the kerfuffle eventually died down as The Donald offered up bigger controversies.

Mr Collins meanwhile remains a true believer in Innate.

"He has not sold a single share and is fully supportive of the acquisition and moving into oncology," Mr Wilkinson says.

In fact, post the dilution, Mr Collins remains one of Innate's biggest shareholder with a 9.35 percent stake, with Cancer CRC subsidiary CTXT Pty Ltd holding 11 percent.

What the FAK?

FAK, we stress, should not be confused with Graham Kennedy's famous crow call (especially with a Kiwi pronunciation).

Rather, FAKs are a target because they regulate the way cancer cells hide from the immune system and thus survive and prosper.

Innate expects at least one of its two candidates, AMP886 and AMP945 to be used in combination with other immunotherapies when the single-agent approach hasn't worked.

Technically speaking, a FAK could be synergistic with checkpoint inhibitors targeting other cancer indicators such as mTOR, SRC and BRAF.

FAK is also implicated in fibrotic diseases, which raises hopes of using the compounds to treat a range of non-cancer ailments.

Innate says the "highly attractive" FAK candidates show "excellent potency and drug like properties, biological selectivity, bio-availability and manufacturing scale-up potential".

The programs are in pre-clinical stage, "but there is a considerable body of data from the pre-clinical cancer models run to date that point to efficacy".

At least one of the drug candidates is expected to be ready for phase-one testing on healthy volunteers within about 12 months.

Innate draws parallels with the Nasdaq-listed Verastem (market cap \$300 million) which is undergoing FAK combination trials with the heavy-hitting Merck and Pfizer.

Targets include pancreatic, ovarian, non-small cell lung cancer and mesothelioma.

Innate contends Amplia's assets are "superior in terms of biological properties and target selectivity".

Prospects and performance

Innate shares vaulted 300 percent after the Amplia deal was unveiled on March 23, but have settled back to where they were.

In March, Innate suffered the opprobrium of being chucked out of the All Ordinaries index, which was a bit, well, ordinary.

Investors value Innate at around \$14 million, a far cry from the old Innate's peak value of \$700 million in early 2017.

Innate says its cash balance of \$2.5 million is enough to last 12 months, but the company expects to raise capital for the phase I testing "in due course".

Meanwhile, there's still potential value with MIS416, which remains on the books, as a cancer drug. While Innate focused on multiple sclerosis, the molecule was supplied to collaborative oncology research programs in Japan and the US.

"We haven't made a song and dance about it, but we never turned our back on cancer," Mr Wilkinson says.

Dr Boreham's diagnosis:

When Dr Boreham subjected Innate to the searing heat of the Crucible in March last year, he cautioned (somewhat self-evidently) that Innate's fortunes would prosper or founder on the strength of the multiple sclerosis trial.

"The outcome is binary: MIS416 must work and the company is not presenting a plan B."

Happily, Innate now does have a plan B but we caution (just as self-evidently) that it's very early days.

In the next one to three months the company will release details of its clinical program and, presumably a capital raising.

But at least the company has regained a purpose in life.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But rest assured, he does give a FAK about the sector.

SIRTEX MEDICAL

Sirtex says it has received an unsolicited proposal from China's CDH Investments to buy it for \$33.60 a share, valuing it at \$1.87 billion, but the Sirtex board backs the Varian bid. In January, California's Varian Medical Systems offered \$28 a share to buy the company, valuing it at \$1.56 billion (BD: Jan 30, 31, 2018).

In March, the company announced Australian, US and German regulatory approvals and said shareholders would vote on the scheme next Monday, May 7 (BD: Mar 27, 2018). Today, Sirtex said the offer was non-binding, indicative and conditional and CDH was an alternative asset fund manager with more than \$US20 billion of committed capital under management.

The company said the indicative proposal was subject to conditions including approval by CDH's investment committee following due diligence and entering into of formal transaction documents, as well as approval form Australia's Foreign Investment Review Board.

Sirtex said it had no engagement with CDH until it received the proposal and had called a Court-approved shareholder meeting to approve the Varian offer for Monday, May 7. The company said it intended to apply to the Court for an adjournment of the scheme meeting to a time and date to be determined.

Sirtex said there was "no certainty that the indicative proposal will result in a binding offer and Sirtex recommends that shareholders take no action at this point in time".

The company said that it would engage with CDH "to further understand the conditions associated with the indicative proposal and, in an expedited timeframe, explore the potential to enter into a binding agreement".

Sirtex said that under the scheme implementation deed with Varian, the engagement with CDH was an exception to its exclusivity obligations.

"At this time, the directors of Sirtex continue to believe the existing scheme of arrangement with Varian is in the best interests of Sirtex shareholders and continue to unanimously support and recommend the scheme," the company said.

Separately, the company said that two class actions relating to claimed losses incurred from a fall in the share price following guidance over dose sales and "allegations of contraventions of the Corporations Act ... in relation to misleading and deceptive conduct and breach of continuous disclosure obligations" would be consolidated into a single proceeding, set for a hearing "sometime in April 2019" (BD: Jan 31, Feb 1, Dec 19, 2017). In a separate announcement, the S&P Dow Jones Indices said it would remove Sirtex from the S&P/ASX 200, subject to "shareholder and final court approval of the scheme of arrangement".

Sirtex climbed \$1.57 or 5.6 percent to \$29.42 with 1.2 million shares traded.

NANOSONICS

Nanosonics says Health Canada has approved its Trophon 2 EPR ultrasound probe disinfection unit.

Last week, Nanosonics said it had US Food and Drug Administration 510 (k) clearance for Trophon 2 (BD: Apr 27, 2018).

Today, Nanosonics chief executive officer Michael Kavanagh said the company could launch Trophon 2 both in the US and Canada by October 2018.

"The new functionality of Trophon 2 places Nanosonics in a good position to establish Trophon as standard-of-care in the Canadian market," Mr Kavanagh said.

Nanosonics was up three cents or 1.2 percent to \$2.59 with 1.7 million shares traded.

RESONANCE HEALTH

Resonance says it has a two-year agreement with Los Altos, California, based Telemedo to distribute an artificial intelligence diabetic retinopathy grading tool.

Resonance said that, with Telemedc, it would target countries in low regulation jurisdictions, where access to ophthalmology services was limited, beginning with Lebanon, Pakistan and Bangladesh, and later China, subject to regulatory clearance.

The company said it would be able to provide screenings for large populations, through primary healthcare providers and it aimed to provide early detection of diabetic retinopathy at an affordable price with efficient outcomes.

The company said the technology was developed by researchers in Australia and used clinical risk factors and images of patients' eyes to provide a diagnostic with an accuracy of more than 92 percent.

Resonance was up 0.4 cents or 17.4 percent to 2.7 cents with 1.3 million shares traded.

FACTOR THERAPEUTICS

The Melbourne-based Acorn Capital says it has reduced its substantial shareholding in Factor Therapeutics to below the five percent substantial shareholder level.

Last year, Acorn reduced to 62,814,562 shares (8.60%) (BD: May 30, 2017).

Today, the company said that between May 30, 2017 and May 3, 2018 it bought and sold shares in Factor Therapeutics with the single largest sale 30,000,000 shares for \$1,047,535 or 3.5 cents a share

In 2016, Acorn became substantial in Factor with 54,611,542 shares or 7.54 percent acquiring the shares at an average price of 3.5 cents a share (BD: May 6, 2016). Factor was unchanged at 3.9 cents.

THE HYDROPONICS COMPANY

Hydroponics says it has leasing rights for a site in northern New South Wales to grow marijuana, as well as supply deals for various cannabis products.

Hydroponics says the leasing agreement was with the Alstonville, New South Walesbased Jenbrook Pty Ltd for the use of its property, while the supply agreements were with Meluka Health, which was 50 percent owned by the West Australian-based Eve Investments.

The company said the supply deal with Meluka included an agreement to supply Meluka with medicinal cannabis for its honey production, as well as an agreement for Hydroponics to use Meluka's extract product for use in medicinal cannabis products.

Hydroponics was up 1.5 cents or 2.2 percent to 68.5 cents with 157 million shares traded.

MMJ PHYTOTECH

MMJ says that 34 percent subsidiary Harvest One Cannabis has agreements to buy Dream Water, a US and Canadian operating company that sells sleep products. In an announcement to the Toronto Stock Exchange, the Vancouver-based Harvest One said it would buy Dream Water for \$US12.5 million (\$A16.6 million) in cash and \$C18.5 million (\$A19.1 million) in shares, for a total of \$C34.5 million (\$A35.7 million). Harvest One said Dream Water produced single serving 2.5 ounce (70.9 gram) liquid sleep "shots", or small drinks, and following the acquisition Dream Water would produce cannabidiol and hemp-based products.

MMJ fell half a cent or 1.3 percent to 37 cents.

QUEENSLAND BAUXITE

Queensland Bauxite has requested a voluntary suspension to follow the trading halt on May 2, pending an announcement regarding an acquisition by subsidiary Medical Cannabis (BD: May 2, 2018).

Today, the company said the deal was expected to be finalized today or prior to trading on May 7, 2018.

Queensland Bauxite last traded at 4.9 percent.