

Biotech Daily

Friday April 6, 2018

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was even on Friday April 6, 2018 with the ASX200 down 0.1 points to 5,788.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and three were untraded.

Avita was the best, up 0.3 cents or 5.3 percent to six cents with 869,296 shares traded.

Admedus climbed 4.8 percent; Acrux and Pharmaxis were up more than three percent; Actinogen, Benitec, Factor Therapeutics, Genetic Signatures, Neuren and Telix rose more than two percent; Mesoblast and Opthea were up more than one percent; with Resmed and Viralytics up by less than one percent.

Compumedics led the falls, down four cents or 11.1 percent to 32 cents with 248,543 shares traded.

Dimerix and Impedimed fell more than four percent; Volpara lost 3.3 percent; Airxpanders, Ellex, Optiscan, Starpharma and Uscom shed more than two percent; with Clinuvel, Cochlear, CSL, Medical Developments, Nanosonics, Pro Medicus and Sirtex down by less than one percent.

DR BOREHAM'S CRUCIBLE: PAINCHEK

By TIM BOREHAM

ASX code: PCK

Share price: 7.8 cents

Market cap: \$64.8 million

Shares on issue: 831,134,587 (254,156,156 in ASX escrow)

Chief executive officer: Philip Daffas

Board: John Murray (chairman), Philip Daffas, Adam Davey, Ross Harricks

Financials (December half): revenue \$27,481*, loss of \$3.4 million (previously \$6.98 million), cash of \$4.7 million (June 30, 2017: \$2.6 million)

Identifiable major holders: Russell David Stewart/Lennard Anthony Lefroy 12.4%, Peters Investments 8.4%, Dr Kreshnik Hoti 4.5%, Mustafa Atee 4.5%, Nviso SA 3.8%.

When your columnist hits his thumb with a misdirected hammer, his neighbors are made well aware of his self-inflicted pain.

Sadly though, many people are unable to indicate clearly that they're in agony, including dementia suffers and kids who can't yet speak.

Enter Painchek, formerly Epat Technologies, which has developed the world's first software application, or "app" as younger people call it these days, to detect facial expressions that are "indicative of the presence of pain".

A 10-second video can recognise nine facial expressions indicative of pain.

Overall, Painchek assesses 42 checkpoints across six domains including facial expression, behavior, body movement and, when possible, vocalization.

Nine checks relate to the face, while the other 33 are assessed by way of a binary 'yes-no' checklist.

The pain is assessed on a 42-point scale, zero to seven being no pain and anything over 16 being ... aaarggh!

"Face is the best way of working out pain, but trying to do it visually is difficult," says CEO Philip Daffas. Facial measures are subjective and skewed by "user bias", he adds.

^{*} Includes sales of \$12,900

Painchek estimates there are 47 million people with dementia globally, 7.5 million in Western Europe, six million in North America and at least 400,000 here.

That's literally a world of pain.

There are also 400 million children aged up to three years, who might scream and shriek like stuck pigs but can't vocalize specific pain.

From PhD to ASX

Painchek emerged from an in-house research project at Curtin University, led by Prof Jeff Hughes, with Dr Kreshnik Hoti and PhD student Mustafa Atee.

The duo founded Epat Pty Ltd (as in Electronic Pain Assessment Technologies) as an inhouse venture, with Epat eventually back-door listing on the ASX in September 2016.

In early 2017 Painchek acquired the global pain assessment rights to the pertinent facial recognition from Swiss artificial intelligence leader Nviso.

The deal was satisfied by Epat paying cash of \$392,500 and issuing 31.25 million of its shares to Nviso.

Nviso's key activity was - and remains - facial research for clients such as advertising agencies, consumer goods companies and even insurance investigators.

In July, the local Therapeutic Goods Administration approved Painchek as a class-one medical device, as did the European regulator.

The company has also been "engaged" with the US Food and Drug Administration.

"We have designed the app taking into consideration the US geriatric pain assessment guidelines and are confident we can obtain FDA approval by the end of 2018," Mr Daffas says.

After a shareholder vote, Epat became Painchek on January 22 this year.

Prof Hughes remains Painchek's chief scientific officer, while Mr Atee is a senior clinical research officer.

In the clinic

Clinical trials to date have involved 753 pain assessments across 74 patients suffering dementia, Alzheimer's or other cognitive shortcomings.

These patients were recruited from five Western Australia aged-care facilities.

The studies showed "excellent" validity and reliability compared to the Abbey Pain Scale, the current standard measure for pain assessment.

The results showed Painchek was able to distinguish the presence of pain in various clinical test conditions "reflective of rest and movement, such as sitting and walking respectively".

Commercial progress

Since October last year Painchek has been selling its enterprize version of the tool to aged care facilities, with two contracts in the bag.

Mr Daffas says the bigger market lies in home care, because most dementia patients aren't hospitalized.

In August, the company finalized an agreement with Hammond Care's Dementia Services Australia, which has 150 consultants using the tool to test 5,000 residential aged care patients across 1,500 nursing homes.

In October, an Apple internet operating system (IOS) app was launched at the Australian National Alzheimer's Conference, aimed at care facilities.

Painchek says: "Two new customers have since purchased licences for their facilities and the company now has a strong pipeline of residential aged care clients of various sizes."

The company is in discussions with a leading residential aged-care facility, to integrate Painchek into its management systems.

So far, this program has been rolled out in Western Australia and South Australia.

Painchek is due to release an android version of the app, which will extend its reach to 80 percent of the residential aged care market and to 99 percent of the overall smart-phone market.

The company also plans to launch a specialist app for kids' pain by the end of calendar 2018.

Singing Spotify's revenue tune

Painchek's revenue model emulates the 'all you can eat' model of the music streaming giant Spotify: a subscription equating to about \$10 per month per resident.

The carers can carry out an unlimited number of tests on an agreed number of patients.

"We are in the early stages of negotiating the larger contracts," Mr Daffas says.

He estimates there are 200,000 relevant people in residential care, but double that number at home.

That's why a consumer version, slated for release by the end of June, is all important.

These customers can expect to pay \$120 annually for the software.

The company then plans to launch in Europe by the end of 2018, but only after the product gains traction here.

Painchek is reasonably well-placed in terms of the folding stuff, having raised \$3.75 million in September 2017.

Dr Boreham's diagnosis:

Should punters take a raincheck on Painchek?

Your columnist is a tad wary of local medical app developers, given the experience of remote respiratory diagnosis company Resapp which reported miserable trial results and is currently re-running the trial.

The heavily-backed Isonea (formerly Karmelsonics and now Respiri) foundered with its asthma diagnosis app, after overestimating the willingness of parents to pay for what they can work out for themselves (their kid is having an asthma attack).

Commercially, it's too early to tell if Painchek is on a winner. But its strategy has been well thought-out to date and we're encouraged by the buy-in of the residential aged-care suppliers.

Mr Daffas is a key element in the story, having been vice prezzo for global marketing at the hugely successful Cochlear.

If Painchek expands its sales globally, it will benefit from a predominantly fixed cost base.

"Because it's software we don't have [cost of goods sold] or expenses," Mr Daffas says.

"It's a really nice, simple business model."

We'll be 'appy' if Painchek is showing real revenue traction within the next six to 12 months.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He swears that the only time he cusses is during DIY mishaps.

INNATE IMMUNOTHERAPEUTICS

Innate says it will begin human clinical trials of the Amplia assets, require a capital raising within 12 months and retain Simon Wilkinson as its chief executive officer.

In March, Innate said it expected to acquire Melbourne's Amplia Therapeutics for its focal adhesion kinase (FAK) cancer program for 18.5 million shares, worth about \$1.3 million, and in a notice of meeting to be held on April 26, said that proposed directors included Telix executive director Dr Christian Behrenbruch, former Cytopia director and Walter and Eliza Hall Institute researcher Dr Chris Burns, former Cancer CRC chief executive officer Dr Warwick Tong and Innate company secretary Andrew Cooke (BD: Mar 23, 28, 2018). Last year, in a clear and transparent announcement, Innate said it would discontinue its MIS416 program trial for secondary progressive multiple sclerosis after a 93-patient, phase Ilb trial showed no meaningful or statistically significant efficacy (BD: Jun 27, 2017). Today, in a series of questions and answers, the company said that it would need to raise capital within 12 months but the current balance sheet would support "pre-clinical activities for the Amplia assets, completion of various MIS416 related activities and working capital needs" for about 12 months.

"We would expect to raise capital for a phase I clinical program and ongoing operations in due course," the company said.

Innate said that "all of the major immuno-oncology leaders are aware of Amplia's FAK assets and their potential", several collaboration opportunities could evolve into commercial partnerships if the data was supportive, but that would be unlikely without initial human data, with an Australian phase I trial about 12 months away to support a regulatory pathway to a US phase II trial.

The company said that data from an earlier pre-clinical MIS416 program in cancer combined with strong human safety data to date, suggested the compound "might have utility in one or more immuno-oncology applications".

"The in-licencing of the Amplia assets will firmly position Innate in the [immuno-oncology] space and the combined team certainly has the relationships and industry connectivity to actively pursue related opportunities for MIS416," Innate said.

The company said that composition of matter and method to treat proliferative diseases such as cancer patents had been granted or were in national phases in major markets, providing coverage, without term extension calculations, until 2033.

Innate said that FAK was a high-potential target in cancer because it had the ability to control the tumor immunity environment, including fundamental regulatory functions that contributed to the way that cancer cells hide from the immune system; and had a synergistic effect with other cancer targets including mTOR, SRC and BRAF for which drug combinations could be boosted with a FAK inhibitor.

The company said that FAK was a potential target for fibrosis, which meant it could be targeted in chronic disease applications.

Innate said that the FAK drug candidates were in pre-clinical development, but there was a body of data from pre-clinical cancer models that pointed to efficacy, as well as a detailed manufacturing package showing that industrializing drug production was viable. The company said that the Amplia FAK inhibitors appeared to have "superior biological properties compared to competing molecules in terms of drug-like properties, biological selectivity, and manufacturability" with the AMP945 drug candidate expected to be well tolerated in humans, while the AMP886 drug candidate had "a multi-action drug profile" with FLT and vascular endothelial growth factor 3 also inhibited by the molecule. "We believe these advantages will enable us to deploy a FAK-targeted asset into distinct and differentiated cancer applications based on these superior properties," Innate said.

Innate fell 1.1 cents or 16.4 percent to 5.6 cents with 3.8 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has raised \$3.4 million from the exercise of its PIQO options exercisable at 20 cents each by March 31, 2018.

Proteomics said that 90 percent of the options were converted by option-holders with directors exercising \$1 million of the options and Alto Capital underwriting any options not exercised (BD: Mar 14, 2018).

Proteomics was unchanged at 23.5 cents.

LBT INNOVATIONS

LBT says it has raised \$487,000 in a share plan at 15 cents a share, following last month's "oversubscribed placement" which raised \$7 million (BD: Mar 6, 2018).

In March, LBT said it hoped to raise an additional \$1 million through the share plan. The company the funds would be used for the commercial launch and development of its automated plate assessment system and working capital.

LBT was unchanged at 14.5 cents.

MEDADVISOR

Medadvisor says it has achieved a "key milestone" of one million connected patients. Medadvisor said that patient user growth was an "important driver of user-based revenue". The company said that its software system helped individuals monitor their medication use, connected patients to their pharmacy, and provided general practitioners access to their personal medication records.

Medadvisor was unchanged at 4.8 cents.

REVA MEDICAL

Reva says investors will vote to issue directors' 474,822 options and 114,000 "restricted" shares.

Reva said it proposed to grant 226,000 options and 114,000 restricted shares to chief executive officer Dr Regina Groves, as well as issue 25,000 options each to directors Dr Ross Breckenridge, Brian Dovey, Robert Stockman and Robert Thomas, with 61,095 options for director Raymond Larkin and 86,917 options for director Dr Stephen Oesterle. The company said the options would be exercisable at the price on the date of the grant, vesting in annual instalments over three years for Mr Larkin and Dr Oesterle, with the options for Dr Breckenridge, Mr Dovey, Mr Stockman and Mr Thomas scheduled to vest one-year following the grant, with 25 percent of Dr Groves' options vesting 12 months after grant and monthly thereafter and the restricted stock units vesting over three years. Last year, Reva approved the issue of 630,000 options and 360,000 restricted shares with less than one percent dissent; and in 2016, investors approved the issue of 826,000 options and 441,000 shares with 3.6 percent dissent (BD: Apr 20, 2016; May 5, 2017). Today, Reva said shareholders would vote on the re-election of directors Robert Thomas, Raymond Larkin and Dr Stephen Oesterle.

The company said shareholders would vote to approve the 10 percent placement capacity, the compensation of executive officers and the issue of securities under the company's equity incentive plan.

The meeting will be held at the offices of DLA Piper, Suite 1100, 4365 Executive Drive San Diego, California on May 17, 2018, at 9:00am (AEST). Reva was unchanged at 39 cents.

RESPIRI (FORMERLY KARMELSONIX, ISONEA)

Respiri has requested a trading halt pending "an announcement in relation to a proposed capital raising initiative".

Trading will resume on April 10, 2018 or on an earlier announcement.

Respiri last traded at nine cents.

MMJ PHYTOTECH

MMJ says that following a mandatory conversion of debentures into stock it holds 53.3 million shares (34.4%) of the Vancouver-based Harvest One Cannabis. MMJ was unchanged at 36.5 cents.

NUHEARA

Nuheara says it has appointed Joel Beilin and Bruce Borenstein to its advisory board, as well as two new regional sales directors.

Nuheara said that the Copenhagen-based Mr Beilin was appointed as chief advisor for audiology while the company's former head of sales, the Florida-based Bruce Borenstein, was appointed chief advisor for consumer electronics.

The company said the Quebec-based David Racicot would become sales director for the Americas and the Singapore-based Renny Ng would be appointed to business development for Asia.

Nuheara said that Gavin James would remain as sales director for the Middle East and Africa

Nuheara fell half a cent or 4.2 percent to 11.5 cents with 28.0 million shares traded.

COGSTATE

Cogstate says it has appointed Prof Pam Ventola as senior science director of its "rare disease and paediatric centre of excellence" in New Haven, Connecticut.

Cogstate said the centre would support its activities in rare disease and paediatric clinical trials

Cogstate chief executive officer Brad O'Connor told Biotech Daily the centre would be housed at its New Haven offices which had about 120 staff.

In a media release to the ASX, the company said Prof Pam Ventola would be appointed senior science director of the centre, while continuing to hold a position at the Yale University School of Medicine.

Cogstate was up 2.5 cents or 3.1 percent to 82.5 cents.