Biotech Daily

Friday August 13, 2021

Daily news on ASX-listed biotechnology companies

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*** AROA: BRIAN, TRACEY WARD TAKE 9.7%, PHIL MCCAW 5.8%**

*** BIO-MELBOURNE PRECISION MEDICINE SYMPOSIUM**

*** AUSBIOTECH: REGENERATIVE MEDICINE REPORT**

MARKET REPORT

The Australian stock market was up 0.54 percent on Friday August 13, 2021, with the ASX200 up 40.7 points to 7,628.9 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 14 fell, four traded unchanged and one was untraded. All three Big Caps rose.

Nova Eye was the best, up five cents or 12.2 percent to 46 cents, with 182,143 shares traded. Neuren climbed 11.6 percent; Pharmaxis improved 10.5 percent; Patrys was up 7.9 percent; Genetic Signatures and Prescient were up more than five percent; Telix was up 4.5 percent; Polynovo, Starpharma, Universal Biosensors, Uscom and Volpara were up more than three percent; Amplia and CSL rose more than two percent; Actinogen, Clinuvel, Cochlear, Opthea, Orthocell, Pro Medicus and Resmed were up one percent or more; with Cyclopharm, Medical Developments and Nanosonics up less than one percent.

LBT led the falls, down 0.8 cents or 7.6 percent to 9.7 cents, with 51,650 shares traded. Imugene lost 6.45 percent; Antisense and Compumedics fell more than five percent; Impedimed was down 4.55 percent; Alterity and Avita were down more than three percent; Immutep, Optiscan and Proteomics shed two percent or more; Cynata was down one percent; with Mesoblast, Next Science and Paradigm down by less than one percent.

DR BOREHAM'S CRUCIBLE: PAINCHEK

By TIM BOREHAM

ASX code: PCK

Share price: 5.5 cents; **Shares on issue:** 1,126,804,799; **Market cap:** $62.0 million

Financials (June quarter 2021): receipts $107,000*****, annual recurring revenue $5.57 million, operating cash outflows $483,000, cash $11.4 million, quarters of available funding 24

***** Government grant revenue

Chief executive officer: Philip Daffas

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

Identifiable major shareholders: Peters Investments 10.02%, J+E Consulting 3.28%, Kreshnik Hoti 3.28%, Mustafa Abdul Wahed Atee 3.28%, Philip Daffas 1.8%.

Not many healthcare providers can claim a 60 percent share of any one market, but that's indeed the penetration of Painchek's automated pain assessment tool in the local aged-care sector.

Those in the know might protest that Painchek enjoys an uncommercial leg-up, in that the Federal Government doled out a $5 million grant for a trial program in 2019.

While Canberra's cash currently accounts for most of Painchek's revenue, CEO Philip Daffas argues the company is far from a protected species: as the funding rolls off, most of the subsidized beds are staying on as full-paying clients.

The company sells to 410 aged care providers, accounting for 1,569 facilities and 129,189 beds (as of June 30).

The Painchek application is also approved in the UK, the European Union, Canada, Singapore and New Zealand (where it's just started selling).

"We are rapidly becoming the most commonly used clinical tool in aged care in Australia," says Mr Daffas. "We were growing prior to the government grant and we have continued to grow since."

From Minquest to Painchek via Epat

Painchek evolved from a company called Epat Technologies, which was vended into listed gold explorer Minquest in 2016.

Painchek was founded in 2010, based on Curtin University intellectual property.

Mr Daffas worked for 30 years in diagnostics, with senior roles at Roche in the UK and Germany. He joined Cochlear in the mid-1990s and headed up the Europe business - and then global marketing - for the hearing implant maker.

In the aged-care space, no one can hear you scream

Painchek is an algorithmic-based device to measure the level of pain experienced by non-verbal older people and infants. The cloud-connected device comes up with a pain score.

Pain assessment is “profoundly difficult” for two groups: those with dementia and cognitive impairment who have lost their ability to self-report pain.

“Pain assessment is hard at the best of times, but extra hard when patients can’t verbalize pain,” Mr Daffas says.

This score is based on 42 checkpoints across six domains including facial expression, behavior, body movements and, when possible, vocalization.

The smart-phone-based device assesses and scores pain levels in real time (about three seconds) and then uploads the results to the internet ‘cloud’. The ability to measure and log the pain scales means that carers can access a more meaningful dashboard that records changes in the patient’s pain levels over time.

Dear Abbey, no offence …

The Painchek application supplements a traditional measure known as the Abbey Pain Scale. This test is proven and well-validated, but it is manual and prone to subjectivity. The nurses or carers also require training.

But there are no hard feelings about Painchek coming up with a better mousetrap, given the scale’s inventor, Dr Jennifer Abbey is an adviser to the company.

In March, the company also recently won local Therapeutic Goods Administration (TGA) and European (CE mark) approval for a newer version called Painchek Universal, which can be used on all patients (not just non-verbal ones).

In the US, the company has lodged an approval application under the Food and Drug Administration’s de novo process, which is for unique but low-risk products.

“We’re about to start clinical trials, which will probably take six to 12 months of work,” Mr Daffas says.

Not taking revenue for grant-ed

In 2019, the Federal Government extended a $5 million grant to fund 100,000 beds for patients with dementia or cognitive impairment, with the contract then extended to June 2021.

At last count, Painchek had 32,349 beds operating under the scheme, with 82,346 paid, but yet to come online. Painchek has a further 14,494 beds subject to normal commercial contracts.

Mr Daffas notes that most contracts are for two to three years, with only the first-year government funded.

The company increased paid beds by 10,000 during the June quarter and expects 15,000 to 20,000 for the whole year, which indeed should more than cover attrition.

Mr Daffas believes attrition will be minimal because it takes time and effort for the facilities to implement Painchek, so they won't dump it in a hurry.

But what's more, the application is bloody helpful (our words).

Seeing you asked …

So, what are the benefits?

An assessment from accounting firm KPMG suggests a meaningful decline in the use of psychotropic medication, because the carers were able to pinpoint the behavior as pain related.

"Sometimes they realize the perceived pain isn't as bad as they [the patients] think it is," Mr Daffas says. "So rather than giving pain medication they can use things like heat packs."

The company works with all the care management systems in Australia, so that the Painchek data can be integrated into broader healthcare information systems.

The tests, by the way can be carried out up to three metres from the patient, a "social caring distance".

Suffer the little children

The flipside of having almost two-thirds market share is that the further upside in the specific aged care market is limited.

But not to worry. As we've mentioned there's the universal application, which applies a numerical score to pain which is able to be verbalized.

Painchek is also pursuing expansion plans based on the pre-verbal kids' market and hospital and home care usage.

The company expects to launch the children's app, Painchek Infants, by the end of 2021.

Mr Daffas estimates there are around 140 million births a year, 60 million of which are to first-time parents. These novice mums and dads face the perennial dilemma of whether the howling is because baby is hungry, or in pain.

And surely, it's your turn to get up this time?

All up there are 400 million children aged between zero and three, which makes for a bigger market than aged care (as are the hospital and home care sectors).

Geography wise, Painchek has mounted in assault on the capacious British aged care market, where it has signed up two content management system (CMS) providers with one more in train.

Painchek first entered the UK market in late 2019, just as a certain virus in Wuhan was creeping out of the wet market.

Currently in the UK, Painchek covers 1,000 beds - a tiny fraction of the addressable market of 450,000 patients - with 1,500 contracted and likely to be deployed in the current quarter.

The pandemic stymied progress, but the company did well with remote sales and training delivery.

UK sales have since returned to pre-pandemic levels.

"We are seeing the UK opening up and good sales potential for the next two quarters," Mr Daffas says.

The company has carried out home care pilot programs in Canada and the UK.

In the local disability space, Painchek is conducting trials with two providers under the National Disability Insurance Scheme.

The company also has Perth-based studies with the Ramsay Hospital Research Foundation, covering frail patients at Perth's Hollywood Hospital. A separate dementia/cognitive impairment study at Joondalup Health Campus is also in the offing.

In Europe, Painchek has a research collaboration with Philips Healthcare covering patients at risk of delirium.

Finances and performances

Painchek's June quarterly report shows somewhat uninspiring revenue of $107,000, which denotes the latest instalment of the Federal Government grant.

As a measure of revenue through the door, but not yet recognized, annual recurring revenue (ARR) is the most closely watched number.

As of June 30, the company had a potential ARR of $5.57 million (the Government program ended on May 31). This ARR is 109 percent higher than a year previously.

In the June quarter, the company added 36,682 beds on a net basis, compared with 45,512 for the entire 12 months to June 30.

Having executed a $10 million capital raising last year, the company held cash of $11.4 million and is debt free.

Sadly, Painchek's progress is not being reflected in the share price, which has declined 57 percent over the last year to a 12-month low.

The stock whooshed to a high of 35 cents in September 2019, on the back of the Federal grant. They have traded as low as 3.0 cents (in April 2019).

Dr Boreham's diagnosis:

A simple story at its core, Painchek is one to shout about as it expands its product reach into the other markets and geographies.

Home care, in particular, could be 10 times the size of the $300 million-a-year aged care market (of which Painchek has penetrated a mere one percent).

The lack of helpful vocalization is closely linked to dementia, which currently affects 50 million older people now and is expected to afflict 75 million by 2025.

Dementia patients account for 50 percent of aged care occupancies and 30 percent of hospital admissions, which also gives a feel for the size of the latter market.

Mr Daffas says rivals will emerge, but there's enough patent protection to defend the company's 'first to market' status.

"We have spent four years getting to market," Mr Daffas says.

"If someone else wants to go down that route there are significant hurdles."

Targeted for 2023, the FDA approval will be a real game-changer.

"Our journey has had significant progress but has only just begun," Mr Daffas says.

"I believe that in the next 12 months the Painchek journey will be transformational."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. We eagerly await the use of Painchek to determine the real level of pain - or staging - exhibited by some of the world's leading soccer players.

SPEEDX

Speedx says the Australian Therapeutics Goods and Administration has approved its severe acute respiratory syndrome coronavirus-2 (Sars Cov-2) laboratory test.
Sydney's Speedx said the Plex-PCR Sars-Cov-2 test detected all known variants and the pathology laboratory test could be purchased by private and government laboratories.
The company said the Australian-developed test had the highest known output of any commercial test on offer and was significantly less expensive than other tests.
Speedx said the test was approved in Europe and the combination of robotics and automated software analysis could support 480 to 1,920 patient samples in eight hours.
Speedx chief executive officer Colin Denver said the company had been supporting laboratories around the world with Covid-19 testing needs.
"Throughout the pandemic, labs across Australia faced supply challenges from many of the global diagnostic providers, and we are passionate about improving sovereign capacity in this space," Mr Denver said.
Speedx said the new test expanded its respiratory portfolio that included the detection of influenza A and B, and respiratory syncytial viruses A and B.
Speedx is a public unlisted company.

HERAMED

Heramed says it has begun a $50 per user per month paid pilot program of its Heracare foetal heart monitor involving 100 expectant mothers.
Heramed said Joondalup Health Campus would pay the technology as a service fee in as recurring revenue.
The company said it was the second paid pilot program to begin this month, following the Obstetrix Medica Group program (BD: May 13, 2021).
Heramed said the program was the last stage of the collaboration with Joondalup to incorporate the Heracare platform to "introduce an innovative model for remote monitoring and care management for pregnant women, allowing for the Herabeat device and foetal heart rate data to be used in telehealth consultations".
Heramed was unchanged at 22 cents.

NYRADA

Nyrada says it further analysis shows that NYX-PCSK9i "significantly increased" the number of receptors responsible for removing cholesterol, in mice.
Nyrada said that in the 35-day mouse study, NYX-PCSK9i was dosed at 50mg/kg as a monotherapy and in combination with the statin drug atorvastatin, or Lipitor, with no adverse effects identified.
The company said the additional results validated the superior performance of NYX-PCSK9i, building on previously reported results.
Nyrada said it hopes to begin a phase I, first-in-human study in mid-2022.
Nyrada chief executive officer James Bonnar said that new data from the study "affirms that NYX-PCSK9i's mechanism of action is through blocking [low-density lipoprotein] receptor degradation caused by PCSK9".
"We're very pleased with these results and our progress to date and look forward to the upcoming results from the safety pharmacology and toxicology studies, which are required prior to our Phase I studies commencing in mid-2022," Mr Bonnar said.
Nyrada was up one cent or 3.3 percent to 31.5 cents.

MGC PHARMACEUTICALS

MGC says all resolutions to its extraordinary general meeting were passed but with more than 15 percent opposition to the issue of 64.2 million director's performance rights.
Last month, MGC said it proposed to issue 27,400,000 performance rights each to managing-director Roby Zomer and executive chair Brett Mitchell, 2,600,000 performance rights each to non-executive directors Dr Stephen Parker and Evan Hayes, and 2,100,000 performance rights each to non-executive directors Nativ Segev and Dr Ross Walker (BD: Jul 9, 2021).
Today, the company said that the greatest opposition was to the issue of rights to Mr Segev with 56,537,481 votes (15.22%) against and 315,050,597 votes (84.78%) in favor MGC said that resolutions on the issue of shares of Medicanl and Cannvalate and were passed easily.
According to the company's most recent Appendix 2A application for quotation of securities, MGC had 2,310,679,974 shares on the issues, meaning that the votes against Mr Segev's performance rights amounted to 2.45 percent of the company, not sufficient to requisition extraordinary general meetings.
MGC was up 0.1 cents or 2.4 percent to 4.2 cents with 1.6 million shares traded.

CANN GROUP, EMYRIA

Cann Group and Emyria say they have agreed to terminate a collaboration for a schedule 3 (S3) over-the-counter marijuana product.
In March, Cann Group and Emyria said they would seek "accelerated registration" of a low-dose, cannabidiol-only capsule from the Australian Therapeutic Goods Administration (BD: Mar 29, 2021).
The companies said at that time that the successful registration of the product as a schedule 3 medicine would result in an "over-the-counter, pharmacist-only" cannabidiol medicine, with Emyria's EMD-003 drug development program using Cann Group's Gelpell micro-sphere technology for the registration for treating unmet needs in mental health.
Today, Cann Group and Emyria said that following a detailed review, both companies had agreed to terminate those arrangements, mutually released each other from obligations and would independently pursue schedule 3 over-the-counter cannabidiol programs.
Cann Group was up one cent or 3.3 percent to 31 cents with 2.15 million shares traded.
Emyria was up half a cent or 2.6 percent to 19.5 cents with 1.95 million shares traded.

CANN GROUP

Cann Group says it will continue its Australian schedule 3 over-the-counter Gelpell marijuana registration program following the separation from Emyria (see above).
Cann Group said the Gelpell microsphere technology was acquired with Satipharm earlier this year for its cannabidiol (CBD) products (BD: Mar 11, 2021) (AVW: Mar 12, 2021).
The company said it would resume its internal program "to support product registration of the Satipharm 50mg CBD capsules as an S3 'Pharmacist Only Medicine' in Australia".
Cann Group said its next clinical trial would be for a pivotal phase III study, to support regulatory approval by the Australian Therapeutic Goods Administration.
Cann Group chief executive officer Peter Crock said that Satipharm CBD capsules were one of the first marijuana products available to approved patients in Australia under the Special Access Scheme and had been used in a variety of medical conditions since 2017.

EMYRIA

Emyria says it has executed an agreement Altasciences to deliver cannabinoid-based medicines for Emyria's EMD-003 Australian and US drug registration program.

Emyria said the new capsules were being developed by the Montreal-based Altasciences clinical research organization to meet both Australian Therapeutic Goods Administration and US Food and Drug Administration quality standards.

The company said its EMD-003 is a schedule 3, low dose cannabidiol drug registration program and would be the first to make use of a new pure synthetic dose form, targeting symptoms of psychological distress.

Emyria managing director Dr Michael Winlo said the company had been "seeking a platform which can deliver a proprietary, cost-effective and FDA-compliant cannabinoid medicine for some time".

Dr Winlo said that working with Altasciences meant that all marijuana products would meet FDA specifications for purity and quality.

"This means the clinical trials and investment required to obtain TGA registrations can also support our FDA registration plans," Dr Winlow said.

"This brings our US registration plans forward significantly," Dr Winlo said.

"Emyria will also have complete ownership over our Australian and US drug development programs, reducing our reliance on third-parties and allowing us to move rapidly towards TGA registration and sales in pharmacies where there is already a great deal of patient and commercial interest," Dr Winlo said.

NUHEARA

Nuheara has requested a trading halt "pending an announcement regarding commencement of a medical device clinical trial".

Trading will resume on August 17, 2021 or on an earlier announcement.

Nuheara last traded at 3.4 cents.

AROA BIOSURGERY

Aroa says it has lodged substantial shareholder notices on behalf of managing-director Brian Ward and Tracey Ward, and director Phil McCaw.

Aroa said that it had undertaken to inform the ASX of becoming aware of a person becoming a substantial shareholder, although there was no requirement for a shareholder of the New Zealand- based Aroa to issue a notice of holdings above five percent under New Zealand law

Last month, Aroa said it had completed an "oversubscribed" $47 million placement at $1.165 a share and hoped to raise $5 million more through a share plan (Jul 29, 2021).

Today, Aroa said that following the completion of the placement, its substantial shareholders were Brian and Tracey Ward with 33,125,800 shares (9.702%), Citicorp Nominees with 27,365,874 shares (8.015%), JP Morgan Nominees Australia with 24,401,862 shares (7.14%), National Nominees with 22,112,806 shares (6.477%) and Phil McCaw with 19,669,229 shares (5.761%).

Aroa was up one cent or 0.9 percent to $1.09.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its September Bio-Symposium will address 'Advancements in precision medicine - opportunities, challenges and economics'.
The Network said the event would provide "insight into the opportunities and challenges faced in various areas of precision medicine, including research, regulations, reimbursement, clinical trials, health economics and commercialization".
The industry organization said that speakers would include Victorian comprehensive Cancer Centre head of clinical research programs Dr Mark Buzza, the University of Melbourne's Prof Clare Scott, the Murdoch Children's Research Institute's Prof Melissa Wake, Melbourne Genomics executive director Prof Clara Gaff, Bio-Melbourne Network chief executive officer Jeff Malone, Deakin University Health Economics chair Prof Cathy Mihalopoulos, Gilead Sciences executive Belinda Wood, Telix chief operating officer Gabriel Liberatore and Iqvia's Sarah Rickwood.
The Bio-Melbourne Network said that the Victorian Government, CSIRO, SeerPharma and Prime Accounting and Business Advisory was sponsoring the BioSymposium.
The Network said the virtual event would be held on September 3, 2021 from 8.45am to 5.00pm (AEST).
For details and registration, go to: https://bit.ly/3scVukl.

AUSBIOTECH

Ausbiotech says regenerative medicine challenges business models, with new approaches required for development, raw materials and personalized medicine.
Ausbiotech said that it was leading the Regenerative Medicine Catalyst, which had produced a report, tilted 'The Regenerative Medicine Value Chain - The Pathway from Discovery to Patient Delivery' prepared by member organization Biointelect Pty Ltd.
The report said that regenerative medicine included gene therapies, cell therapies and tissue-engineered products intended to regenerate or replace injured, diseased, or defective cells, tissues, or organs to restore or establish function and structure.
The industry organization said that the other five members were Medicines Australia, Cell Therapies Pty Ltd, Novartis Australia New Zealand, Research Strategies Australia, and MTP Connect.
Ausbiotech said the Regenerative Medicine Value Chain report considered the chain of activities involved in regenerative medicine therapy development, including: research capabilities, funding, streamlined approvals and incentives, pathways to patient delivery and data-driven approaches.
"Advancing [regenerative medicine] in Australia offers patients timely access to cutting-edge and potentially life-saving … therapies by promoting a thriving domestic … sector and ensuring that Australia remains a priority market for global developers," the industry organization said.
Ausbiotech said that Australia had "a strong and vibrant" regenerative medicine industry with a clinical trials framework, translational research and clinical centres.
The organization said that more than 60 companies in Australia were developing products with more than 130 clinical trials in progress.
Ausbiotech said that the Regenerative Medicine Catalyst received matched funding through MTP Connect's Growth Centre Project Fund Program.
https://www.ausbiotech.org/documents/item/664.