Biotech Daily

Friday September 8, 2023

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: CYCLOPHARM UP 10%;**
- STARPHARMA DOWN 7%

*** DR BOREHAM'S CRUCIBLE: PAINCHEK**

*** PROTEOMICS BLOOD TEST FOR OESOPHAGEAL CANCER**

*** RECCE REQUESTS 'CAPITAL RAISE' TRADING HALT**

*** IMRICOR TO RELEASE 7.8m VOLUNTARY ESCROW SHARES**

*** LIVING CELL BECOMES ALGORAE; CODE CHANGE TO 1AI**

*** BIO-MELBOURNE OCTOBER 'PRECISION HEALTHCARE' SYMPOSIUM**

MARKET REPORT

The Australian stock market fell 0.2 percent on Friday September 8, 2023 with the ASX200 down 14.3 points to 7,156.7 points.

Nineteen of the Biotech Daily Top 40 stocks were up, 14 fell, five traded unchanged and two were untraded.

Cyclopharm was the best, up 24 cents or 10.0 percent to $2.65, with 9,367 shares traded.

Impedimed, Proteomics and SDI climbed more than six percent; both Alcidion and Prescient improved 4.35 percent; Cynata and Polynovo were up more than three percent; Micro-X and Nova Eye rose more than two percent; Antisense, Avita, CSL, Immutep, Mesoblast, Neuren and Next Science were up one percent or more; with Cochlear, Nanosonics, Telix and Volpara up by less than one percent.

Starpharma led the falls, down one cent or 6.9 percent to 13.5 cents, with 1.9 million shares traded.

Resonance lost 5.8 percent; Actinogen fell four percent; Emvision, Kazia, Opthea and Paradigm shed more than two percent; Atomo, Clinuvel, Dimerix, Imugene, Medical Developments and Resmed were down more than one percent; with 4D Medical and Pro Medicus down by less than one percent.

DR BOREHAM'S CRUCIBLE: PAINCHEK

By TIM BOREHAM

ASX code: PCK

Share price: 2.8 cents

Market cap: $36.3 million

Shares on issue: 1,297,989,542

Financials (Year to June 2023): revenue $1.95 million (up 99%), loss of $7.57 million ($5.72 million deficit previously), cash of $2.51 million (down 59%)

June quarter 2023: revenue $605,000, customer receipts $737,000, cash outflows $549,000, cash on hand $2.51 million, quarters of available funding 4.6

Chief executive officer: Philip Daffas

Board: John Murray (chair), Mr Daffas, Ross Harricks, Adam Davey, Cynthia Payne

Identifiable major shareholders: Peters Investments 9.1%, J+E Consulting 2.9%, Kreshnik Hoti 2.9%, Mustafa Abdul Wahed Atee 2.9% Philip Daffas 1.7%.

Drug developer Mesoblast's recent epic fail with the US Food and Drug Administration (FDA) has prompted moments of introspection for other ASX-life science plays due to front the feared regulator with approval applications.

In the case of the stem cell therapy developer, Mesoblast had all the right vibes that the FDA would approve its marketing application for its paediatric graft-versus-host disease therapy.

But it was knocked back for a second time.

Painchek chief Phil Daffas isn't taking anything for granted as the pain management monitoring company readies a small clinical trial to support its planned FDA entreaty under the de-novo (new device) route.

Still, Mr Daffas would be mightily surprised if the regulator said no, given the low-risk nature of the tool that is widely used in aged-care centres here and in the UK.

"The [device] protocol has already been refined three times with FDA inputs," he says.

Expected by mid-2024, FDA clearance would expand Painchek's addressable market by two million beds, compared with around 600,000 beds currently.

We’re the voice

Painchek’s eponymous device is an algorithmic-based tool to measure the level of pain experienced by non-verbal older people, typically those suffering dementia.

“We give a voice to people who cannot reliably verbalise their pain,” Mr Daffas says.

By profiling the patient’s face, within three seconds, the software application comes up with a pain score based on nine facial expression measures.

These facial scores add to a manually-derived checklist, based on the Abbey pain scale developed by Adelaide pain-ologist Dr Jennifer Abbey.

Mr Daffas equates the tool to a digital thermometer relacing the old mercury one: the purpose is the same but the new version works better.

“In effect we have taken the Abbey pain scale and automated the facial assessment aspect and built on observational pain assessments.”

As an adviser to the company, Dr Abbey is evidently unfazed at the prospect of redundancy.

So far, Painchek has recorded more than three million pain assessments, which enables analytical reports to be provided to the nursing homes.

“They can track pain management across all of their facilities and use it for auditing and accreditation purposes,” Mr Daffas says.

From lab bench to nursing home

Painchek was called Epat Technologies - as in Electronic Pain Assessment Technologies - which was vended into ASX-listed gold explorer Minquest in 2016.

Epat was founded in 2010, based on a Curtin University research project and the company changed its name to Painchek in early 2018.

Mr Daffas had a three-decade career in health diagnostics and devices, notably at Roche and Cochlear.

“The uni approached me and asked whether the project was commercial and scalable and we worked with the research team to build the model,” he says.

“I bring to the table the experience of being able to globalise a business, which most Australians don’t have.”

Several members of the Curtin University project have stayed for the ride, including Painchek chief scientific officer Jeff Hughes.

In 2017, company won Australian Therapeutic Goods Administration (TGA) and Conformité Européenne (CE) mark approval.

These gatekeepers then approved a newer version called Painchek Universal, which can be used on all patients (not just non-verbal ones).

Shed the meds

Mr Daffas says that at least 60 percent of aged care residents cannot reliably communicate their pain levels, because of cognitive impairment.

Often these residents act aggressively or strangely, but this could be because of uncommunicated pain. As a result, anti-psychotic drugs and sedatives are often inappropriately dispensed.

“If you can diagnose the pain first and treat it, you can often change the behavior,” he says.

The operator of 24 homes and 1,300 beds, Orchard Care in the UK Midlands reduced anti-psychotic medication use by 10 percent by using Paincheck, with a 30 percent reduction in sedative dispensing.

In some cases, Painchek has determined that pain can be less than what had been assumed, resulting in lesser use of constipation-inducing opiates - and laxatives.

With ‘verbal’ patients, the Painchek Universal iteration is handy for digitally recording pain improvement (or otherwise).

Where there’s pain, there’s gain …

Painchek already has a decent foothold in the Australian aged care sector, claiming a circa 25 percent market share.

Drilling down a little, the company so far has signed up 700 aged care facilities accounting for 50,000 beds, in a total market of around 220,000 beds. The clients pay a subscription of $50 per bed per year and can carry out as many assessments as they like.

In the UK, the company has gone from 5,000 beds to 20,000 beds across 300 aged care homes in the last 12 months, in an overall market of 440,000 beds.

“That’s less than five percent of the market, but there’s no reason why we also can’t get to 25 percent of the UK market in a similar time frame as we did in Australia,” Mr Daffas says.

Painchek also has a presence in New Zealand and Canada.

Standing on our own two feet

Investors idly perusing Painchek's numbers might get the impression the company has gone backwards, as it covered around 80,000 beds in Australia two years ago.

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

With these subsidies long gone, Mr Daffas is pleased that so many clients agreed to continue to roll-over their contracts on a user-pays basis.

Painchek's clients range from having 40 beds to more than 3,000 beds, but market consolidation means the typical client is getting bigger.

Local users include Baptistcare, Allity, Ozcare and Anglicare.

Partnering in the US …

To support its FDA application, Painchek will carry out a small study of about 100 aged care patients who reflect the country's racial make-up.

The study will be done by a contract research organisation at between five and 12 nursing homes in three states.

Post-approval, Painchek's sales representatives can't just rock-up to the facilities and do the hard sell: they won't get far if the devices are not integrated with the provider's established care-management systems.

Recognising this, Painchek has struck an agreement with aged care supplier Point Click Care to integrate the software with one million US aged-care beds.

"They are the care-management system provider that documents the patient records and information," Mr Daffas says.

"If you do a pain assessment at any of their facilities it documents automatically into their system.'

Painchek has also a non-exclusive tie-up with pain specialist Ethos Labs, by which Ethos will sell Painchek at the point-of-care via its own sales force.

Painchek also has a compact with Intersystems, a provider of 'middleware' to hospitals in the US, the UK and here.

And elsewhere …

Painchek has integration agreements with 10 intermediaries including Telstra Health and Leecare Solutions in Australia. Both of these providers cover about 40,000 beds.

Mr Daffas says the local integrators provide a "pathway" to 180,000 beds, while the UK providers cover 285,000 beds.

"So, in effect we have less than 10 percent of the beds in the UK relative to what these groups could allow us to access," he says.

Easing the pain for parents

Parents of infants often don't know whether the little one is howling because of pain or because they are hungry or tired (or many other possible reasons).

"They can test for fever with a thermometer, but they can't test for pain," Mr Daffas says.

Painchek has been working on an infant software application that would remove the guesswork, by applying the facial scan in a similar way to aged-care patients.

An interesting tweak is a vocalisation feature that can distinguish whether the howl is a "cry of pain or not pain".

This means Painchek potentially could be incorporated into baby monitors, thus opening a huge new market.

Mr Daffas says the algorithm was 'trained' on kids undergoing painful procedures, such as vaccinations.

"We weren't beating them up," he assures us - quite unnecessarily, of course.

Finances and performances

Painchek recorded $604,000 of customer revenue in the June 2023 quarter, six percent more than the March stanza and 81 percent higher year-on-year.

Annual revenue doubled to $1.95 million, with receipts up 90 percent to $2.24 million.

Annual recurring revenue (ARR) doubled to $3.4 million, with a retention rate of 85 percent.

The company recorded net cash outflows of $6.3 million for the year and $549,000 for the quarter.

At the end of June, Painchek had a skinny cash position of $2.5 million and the company "will raise more funds at the appropriate time".

Mr Daffas says signing up to180,000 to 200,000 beds would get the company to break-even level.

If the company achieved 50 percent of the Australian and UK markets - roughly 100,000 beds and 220,000 beds respectively - the company would be comfortably profitable.

"All the rest is gravy," Mr Daffas says - not a reference to nursing home food but the high profit margin on the product.

Painchek shares peaked at 35 cents in 2019 on the back of the Federal Government grant, but are wallowing near record lows. However, the shares have held their ground over a torrid 12 months for the sector.

Dr Boreham's diagnosis:

Mr Daffas describes Painchek as the most popular digital clinical tool in Australia - and we can't argue with that.

"We have had a wonderful year," he says. "There is no Federal Government funding overhang and it is all pure commercial business now."

The company estimates the global aged-care market at six million beds, worth $300 million annually.

But the home care sector could be worth 10 times more than that, while management sniffs a $1 billion opportunity in the hospital sector. The infant market will be child's play if it pans out as expected.

Meanwhile, Painchek is not pained by a rival: the real competition being the old paper-based pain assessment tools.

While the coast is clear, the company needs to go hard on the opportunities before inevitable competition emerges.

Fundamentally, the Painchek story is simple and the benefits of the device are crystal clear - especially relative to the modest cost for aged-care operators relative to other burdens. As with all device plays, commercial success will come down to the right execution such as choosing the right partners and geographies.

There will be pain along the way, but we are confident the company can grin and bear it.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. When he is pain, it will be clearly enunciated and everyone will know about it.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says its oesophageal adenocarcinoma blood test correctly identified 89 percent of patients with the disease and 92 percent without the disease.

Last year, Proteomics said that a 302-patient study of its oesophageal adenocarcinoma test showed “strong diagnostic performance”, with an up-to 90 percent detection rate (BD: Sep 27, 2022).

At that time, the company said the prototype test was an easy-to-use test using biomarkers, or protein ‘fingerprints’ in the blood, and could be used to target Barrett’s oesophagus, a pre-malignant condition associated with increased risk of oesophageal adenocarcinoma.

Proteomics said at that time that the study first analyzed a development cohort of samples from 253 people with either oesophageal adenocarcinoma, Barrett’s oesophagus, Barrett’s oesophagus with high grade dysplasia, and health controls to attain optimal performance.

The company said last year that the then prototype had 90 percent sensitivity and 64 percent specificity, and for Barrett’s oesophagus versus oesophageal adenocarcinoma it had 80 percent sensitivity and 89 percent specificity.

Today, Proteomics said that further analysis of its test, named Promarkereso, used 249 clinical samples from people with oesophageal adenocarcinoma, Barrett’s oesophagus, Barrett’s oesophagus with high grade dysplasia and negative controls.

The company said the blood test measured the glycol-protein biomarkers it had developed and showed the diagnostic model for discriminating disease severity “performed strongly” in the validation cohort.

Proteomics said that the test had 80 percent sensitivity and 93 percent specificity in negative controls versus oesophageal adenocarcinoma, and 59 percent sensitivity and 93 percent sensitivity for negative controls versus oesophageal adenocarcinoma and Barrett’s oesophagus with high grade dysplasia.

The company said the results applied its ‘traffic light’ scoring system to categorize patients as green (low risk), amber (moderate risk) or red (high risk) for oesophageal adenocarcinoma.

Proteomics said the study titled ‘A novel serum glycoprotein biomarker panel for screening of esophageal adenocarcinoma and surveillance of Barrett’s esophagus’ would be presented at the International Society for Diseases of the Esophagus congress in Toronto, from September 8 to 10, 2023.

The company said that the standard-of-care screening method for oesophageal adenocarcinoma currently required an endoscopy procedure that cost $US2,750 ($A4,306) a patient.

Proteomics managing director Dr Richard Lipscombe said the company had refined the Promarkereso’s diagnostic models which now showed strong discrimination at early and late stages of the disease.

“This means we could have a simple blood test to determine who would benefit from an endoscopy,” Dr Lipscombe said.

“We believe that such a test would garner significant clinical and commercial interest should it be further validated,” Dr Lipscombe said.

Dr Lipscombe said that next steps were streamlining the test’s biomarker measurements to be suitable for US laboratory developed test pathway, confirming the test’s clinical performance in a further independent cohort and conducting economic health benefit models to show how the test could improve treatment decisions and patient outcomes.

The company said it expected these steps to be completed by July 2024.

Proteomics was up six cents or 6.9 percent to 93 cents.

RECCE PHARMACEUTICALS

Recce says it has requested a trading halt “pending the release of an announcement relating to a proposed material equity capital raise”.
Trading will resume September 12, 2023, or on an earlier announcement.
Recce last traded at 65 cents.

IMRICOR MEDICAL SYSTEMS

Imricor says it will release 7,755,391 placement shares and the equivalent Chess depository interests (CDI) from voluntary escrow on September 15, 2023.
Last year, Imricor said an “oversubscribed” US placement raised $2.92 million at 38 cents a share and the US stock would be subject to a holding lock for 12 months, after which each share would be convertible to a CDI (BD: Sep 14, 2022).
According to its most recent filing, Imricor had a total of 159,424,016 shares on issue.
Imricor was unchanged at 61 cents.

LIVING CELL TECHNOLOGIES (TO BE ALGORAE PHARMACEUTICALS)

Living Cell says it has formally changed its name to Algorae Pharmaceuticals with its ASX code to be changed to 1AI from Monday, September 11, 2023.
In July, Living Cell said Algorae was a unique word over which the company had lodged a pending trademark which was derived from “the term algorithm, which underpins artificial intelligence” (BD: Jul 11, 2023).
Later that month, the company said it had filed a provisional patent for a marijuana-based combination drug AI-116 for the treatment of dementia (BD: Jul 26, 2023).
Living Cell was unchanged at 1.4 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its October symposium will discuss precision healthcare to improve the lives of people with or at risk of cancer and rare diseases.
The Bio-Melbourne Network said the October ‘Bio-Symposium’, titled ‘Precision Healthcare: The New Normal’ would discuss “the developing role of precision healthcare to improve health outcomes for people living with cancer and rare diseases, or at risk of developing cancer”.
The Network said that the event would cover “the latest collaborations and approaches, how organizations, systems and bio-informatics can help healthcare professionals match patients to the right therapies and clinical trials, and how these developments are ushering in a new era of personalized treatment strategies.
Bio-Melbourne said the event would be held at Monash College, Level 2 Auditorium, 750 Collins Street, Docklands, Melbourne, on October 4, 2023 from 8:45am to 6:30pm, including networking.
For details and registration, go to: www.bit.ly/3YRaa96.