Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Painchek

By TIM BOREHAM

ASX code: PCK

Share price: 5.9 cents

Shares on issue: 2,072,504,844

Market cap: $122.3 million

Financials (Year to June 2025): revenue $3.36 million (up 26%), loss of $7.69 million ($8.3 million deficit previously), cash of $1.61 million (down 49%) ahead of $7.5 million capital raising

Chief executive officer: Philip Daffas

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

Identifiable major shareholders: Peters Investments 6.5%, Double Red Investments (2.4%), Harlex Farms (TH Martin Family) 2%, Dr Kreshnik Hoti 1.8%, Philip Daffas 1.3%.

Medical device makers have been skipping through a purple patch with the US Food and Drug Administration (FDA), with the agency recently bestowing approvals to Orthocell (its Remplir nerve wrap), EBR Systems (its Wise heart assist device), Echo IQ (heart disease diagnosis) and Nanosonics (its next-gen probe sterilization device).

Painchek this month joined this pantheon of device greats, with the agency clearing the company's eponymous software application-based device, for measuring pain when the subject is unable to express it.

Think of dementia suffers in aged-care homes.

While one might think the FDA has become munificent and more rapid in its decision-making approach, the approval was hardly an overnight achievement.

Painchek first engaged with the agency in 2019 and then suffered two years of pandemic disruption.

Remarkably, given the FDA's recent ructions, the company has dealt with pretty much the same review team all the way through.

The clearance is even more notable because the company lodged its entreaty under the de-novo (new device) route, which is harder than the predicate 510(k) pathway favored by most device makers.

Painchek chief Philip Daffas dubs the clearance as a "transformative achievement, uniquely positioning us to enhance pain assessment and management in the world's largest healthcare market".

He adds: "De-novo is a new standard, a new category, a new 'everything'. We will be unique, in a significant market with no competition."

The device even sports its own FDA code: SGB.

This "formally recognizes Painchek as a unique, first-of-its-kind, medical device for pain assessment."

The FDA decision opens Painchek to a market of three million aged-care beds, with an initial addressable market of $US100 million ($A150 million) a year.

The company also eyes the broader US aged care market, notably home care and hospitals.

About Painchek (the device)

Painchek is the world's first artificial intelligence-driven digital software application (app) to detect and measure pain.

The initial indication is for pain suffered by nursing homes residents unable to enunciate their discomfort, but the company also targets the pre-verbal kids' market (see below).

The process involves the carer capturing a three-second image of the resident's face. This detects the presence of up to nine facial pain expressions.

Combined with other clinical resident observations, the tool produces an overall pain score and severity rating.

To date, carers have used manual subjective processes such as the manual Abbey Pain Scale, developed by Adelaide pain-ologist Dr Jennifer Abbey.

The Australian Therapeutic Goods Administration (TGA) and the European device gatekeeper cleared Painchek in 2017.

To date, nursing homes have recorded around 12 million pain assessments with the tool.

About Painchek (the company)

Painchek originally was known as Epat Technologies - as in Electronic Pain Assessment Technologies.

The company was vended into ASX-listed gold explorer Minquest in 2016, which was seeking a different, er, quest.

(It wouldn't be so keen on diversifying these days, with the gold price at $US4,000 an ounce and all that …)

Epat was founded in 2010, based on a Curtin University research project.

The company changed its name to Painchek in early 2018.

Mr Daffas cut his teeth in health devices across numerous roles over three decades, including at Roche and Cochlear.

"The Uni approached me and asked whether the project was commercial and scaleable and we worked with the research team to build the model," he says.

"I bring to the table the experience of being able to globalize a business, which most Australians don't have."

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. Nowadays, Painchek stands on its own feet.

As of June 2025, Painchek had signed up licences for 110,000 beds, across 1,900 nursing homes in Australia, New Zealand, Canada and the UK.

Of these, the company has implemented 71,000.

The company already has a decent foothold in the Australian aged care sector, claiming a circa 35 percent market share: 75,000 licences across 200,000 beds.

Local users include Baptistcare, Bolton Clarke, Ozcare and Anglicare.

The company claims coverage of 40,000 of the UK's 440,000 beds (nine percent penetration).

To market, to market

Painchek is “the first and only regulated medical device available to assess pain in people who cannot reliably verbalize, within the US nursing home and long-term care market”.

Given the elongated approval time frame, the company has had a long time to plot its US market entry.

It’s certainly not going it alone.

As well as building its own US sales team, Painchek has an integration partnership with long-term care supplier Point Click Care, covering more than one million US beds.

A care-management provider, Point Click Care documents patient records and information.

Painchek also has an integration and reseller tie-up with Elder Mark, which will sell the device alongside other products.

Elder Mark has a customer base of up to 400,000 beds in the US and Canada.

Combined, these parties cover 60 percent of the North American long-term care market.

The company also eyes the broader aged care market sector, notably home care and hospital.

Including these facilities, the US addressable market enlarges to $US370 million ($580 million).

Finances and performance

Painchek recorded $3.36 million of customer revenue in the year to June 2025, up 26 percent.

Australia accounted for about two-thirds of this income, with the UK chipping in most of the remainder.

Painchek’s net loss narrowed to $7.6 million, from $8.3 million previously. But the company says it is operationally break-even in Australia and the UK.

Annual recurring revenue (ARR) across the activated licences climbed six percent to $3.6 million. Across the total licences, ARR climbed 18 percent to $5.4 million.

With the FDA application done and dusted, research and development expenses eased 21 percent to $3.78 million.

At the end of June, Painchek had cash of $1.6 million.

In July the company raised $7.5 million in a placement at 3.4 cents apiece, which should provide enough capital for the US rollout.

The company describes US reimbursement for pain management as “excellent”.

Locally, the nursing home clients pay a subscription of $50 per bed per year, with an equivalent fee of GBP30 per annum in the UK.

Pending FDA clearance, Painchek has lined up its maiden US client (albeit a small one).

“We believe we will get a premium price in the US,” Mr Daffas says.

Over the last 12 months Painchek shares climbed from a low of three cents in late June this year, to the post-approval zenith of eight cents on October 10.

Painchek shares peaked at 32 cents in October 2019.

Only the beginning

While Painchek will focus on bedding down the US market - pardon the pun - the FDA clearance could be an entrée to other geographies that accept the agency’s imprimatur.

The company is especially interested in Japan, the world’s second-biggest aged care market with 1.1 million beds. Japan is famed as the most rapidly ageing developed country.

Another country of special interest, Germany has 800,000 aged-care beds.

Other countries in which Painchek might leverage FDA clearance include Brazil and the United Arab Emirates.

And did anyone mention kids? The Japanese might not be having too many of them, but 400 million babies are born globally annually - 150 million to first-time-parents.

Painchek has launched a variant in Australia, Infant App, for these pre-verbal kids.

After all, it’s hard to know whether the little ones are howling because they are in pain, hungry or need a nappy change.

The company dubs the launch, via the Apple Store, as a success and is now pursuing broader expansion across “multiple markets”. The app costs a one-off $99, or $15 per month with a one-month free trial option.

“Given the personal nature of infant health, a considered rollout is important to build credibility amongst parent and healthcare audiences,” the company says.

The company is developing partnerships with healthcare retailers, paediatric healthcare providers and consumer health platforms.

Lifting the kilt on evidence

Detecting pain is one thing; proving the benefit in doing something about it is another.

One result of Painchek use is a decline in prescription drug use and improved quality of life.

Plus, savings to the health system. Just ask the Scots.

In September, Painchek said the Scottish Care Inspectorate had completed an independent study of Painchek, which confirmed “significant clinical benefits across a range of areas”.

These included a 25 percent decrease in the use of analgesics, a 34 percent reduction in laxative use and a 21 percent fall in anti-depressant prescriptions.

The patients also recorded a 40 percent fall in, er, falls and a 27 percent decline in “dependency”.

The pilot program was government-funded and independently evaluated by Edinburgh Napier University, in collaboration with the Scottish Care Inspectorate.

The analysis estimates a circa GBP66 million ($A134 million) benefit to the system, based on implementing Painchek across 60 percent of Scottish care homes.

Painchek's largest client in those parts, Scotland Renaissance Care took part in the trial. Renaissance operates 18 care homes across the country, with about 750 residents.

Painchek also carried out a study of 105 nursing home residents, across five sites in Iowa and New York.

The results confirmed the device’s accuracy in detecting no pain as well as low, moderate and severe pain.

Dr Boreham’s diagnosis:

We’re now hearing Painchek’s mission to “give a voice to people who cannot reliably verbalize their pain” - loud and clear.

Assuming similar pricing to Australia and the UK, penetrating 10 percent of the US aged-care home market would deliver $15 million of annual revenue.

“We believe we will get a higher price in the US,” Mr Daffas says.

More broadly, the global aged care market equates to 8.26 million beds with an “annual market value” of $425 million.

The at-home market for dementia patients eclipses that, at $3.65 billion.

The kids' market could be even bigger again: a one percent penetration (four million kids) equates to annualized revenue of $336 million.

Painchek enjoys the pain-free scenario of having no competition, although inertia can be a powerful force.

By that we mean that care homes continue with the manual approach because front-line staff are used to it. Many parents - even first timers - might be happy to trust their instincts.

But with the need for digitized record keeping in the aged care sector, Painchek looks poised for meaningful short to mid-term expansion without too many growing pains.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He does not share the famed view of the Dutch that pain is character building and a normal part of life.