

## Smart opportunity in pain relief

#### Setting global benchmark in pain assessment

PainChek is a Sydney-based pain assessment tool provider. Considering lack of any global benchmark in pain assessment, PainChek is expected to set a new global standard with its innovative product. The artificial intelligence (AI)-based mobile app uses facial expression to map and quantify pain. Considering millions of patients suffer from dementia globally and cannot explain pain explicitly, this utility app has exponential growth opportunity.

#### **Investment case**

PainChek can address large global markets in both dementia patients and in children. The PainChek pain assessment tool is a medical device that has been developed from a concept to a market reality within two years, receiving peer-reviewed publications and regulatory clearances in the process. It has now been commercialised and is experiencing rapid growth in sales and clincial use in Australia, with immediate overseas opportunities including Europe and Asia to be addressed soon. PainChek's business model is low cost, characterized as it is by partnerships with 3rd party software suppliers globally. PainChek's team has proven experience in the medical device space.

#### Valuation range A\$0.08-\$0.16 per share

We currently value PainChek at 8 cents per share base case and 16 cents per share optimistic case using a DCF approach with what we think are conservative assumptions on commercial expansion. Our valuation relates to what PainChek has achieved over the last two years in bringing its app into Residential Aged Care in Australia. Should the management be able to expand market outreach aggressively, launch a child version of the app commercially, and gain additional regulatory clearances for US and global launches, there will be considerable upside to our current valuation.

Share Price: A\$0.044

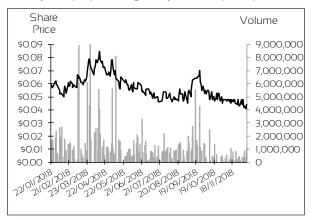
ASX:PCK

Sector: Healthcare 12 December 2018

Market Cap. (A\$ m)	36.9
# shares outstanding (m)	837.9
# share fully diluted (m)	1,014.8
Market Cap Ful. Dil. (A\$ m)	44.7
Free Float	100%
12 months high/low	A\$0.085 / A\$0.041
1/3/12-month performance	-13% / -26% / -16%
Website	<u>painchek.com</u>

Source: Company, Thomson Reuters and Pitt Street Research

#### Share price (A\$) and avg. daily volume (r.h.s.)



Source: Thomson Reuters, Pitt Street Research

Valuation metrics	
DCF fair valuation range (A\$)	\$0.08 - \$0.16
WACC	10%
Assumed terminal growth rate	3%

Source: Pitt Street Research

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#### **Introducing PainChek**

PainChek, a Sydney-based digital healthcare company, develops and commercializes mobile-based medical device applications that enable automated and intelligent pain assessment of individuals who are unable to communicate their pain. The tool empowers carers to accurately assess and manage pain across environments — at home or medical centers. Its unique app-based tool is designed and developed to transform pain management using artificial intelligence (AI) and smart telephony. The initial concept was created by Curtin University employees, Professor Jeff Hughes, Mustafa Atee, and Dr. Kreshnik Hoti, the AI-based automated tool aims to eliminate subjectivity and manual bias while assessing pain. This is useful for dementia patients and preverbal children. PainChek is now a first-in-class pain assessment medical device that has already obtained regulatory clearance in Australia and Europe.

#### A brief history

PainChek was initially developed by Electronic Pain Assessment Technologies (ePAT) Pty Ltd which was owned by Curtin University. The company MinQuest Limitedwas engaged in mining activities across Australia. The firm's earlier activities were limited to mineral exploration for gold and base metals in Western Australia. In early 2016, the board reviewed the continued uncertainty regarding the outlook for the mining and metals sector, and the impending challenges for resource companies. Consequently, MinQuest decided to acquire ePAT Pty Ltd from Curtin University and diversify. In September 2016, under a reverse merger agreement, ePAT completed the takeover of MinQuest, changed its name to ePAT Technologies Ltd and shifted its entire business focus to developing and marketing the pain assessment tool. In the process a new Board of Directors and Management team were appointed with global healthcare and digitial technology backgrounds. In January 2018, the company changed its name to PainChek Ltd for consistency with the PainChek App brand.

#### How does PainChek work as an electronic pain assessment tool?

PainChek technology uses cameras in smartphones and tablets to record a brief video of the person – this is analyzed in real time via facial recognition software to detect the presence of micro-expressions that indicate the presence of pain (Figure 1).

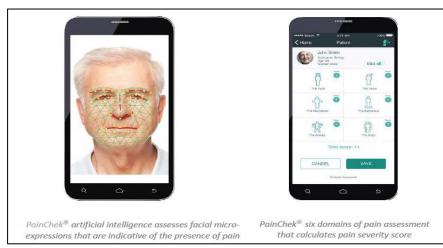
Built upon an Al-based market-leading facial emotional assessment technology from nViso, PainChek deploys a secure and validated medical device in the form of a mobile app. The app automatically recognizes facial muscle movements that indicate pain. This data is then integrated with other non-facial pain indicators, including vocalizations, behaviors, and movements, to generate a pain severity score. A total of 6 domains of assessments are covered to calculate this score. Due to speed, ease of use, reproducibility, and ability to quantify, PainChek as a utility tool is gaining rapid significance in pain management.

Mobile app that uses AI to assess and monitor pain

PainChek's facial assessment technology is exclusively licensed from nViso which uses visual intelligence to detect and predict human behaviour



Figure 1: The PainChek solution



Source: Company

#### Ten reasons to consider PainChek

- 1) Pain is often poorly assessed, documented, monitored, and managed. Undetected and untreated pain can adversely impact the quality of care. Faulty detection of chronic pain can lead to incorrect prescription of antipsychotics. Hence, a pain assessment tool is a necessity, especially for old-age care and child care centers/medical homes/hospitals, making the PainChek app a vital tool.
- 2) PainChek is a one-of-its-kind facial recognition tool it is digital, automated, and based on AI. It is an easy-to-use app that can record and store expressions to deduce the amount of pain. PainChek can work offline as well (for recording the expressions).
- 3) Globally, there is a lack of quality benchmarks for pain assessment. PainChek is expected to set global standards by quantifying pain for people who cannot communicate effectively, e.g., dementia patients and preverbal children.
- 4) The company has already obtained regulatory clearance for 2 of the largest markets in the world Australia and Europe. Trials of the app have been successful for dementia patients, but its functionality for children is yet to be approved which offers extra growth potential.
- 5) Dementia is a major old-age affliction. Millions of patients across the globe suffer from this disease. Consequently, there is a massive untapped market for PainChek. It is imperative to note that dementia patients and preverbal children are those who suffer the most from chronic pain, and thus regularly require efficient pain management systems.
- 6) PainChek can generate revenue from multiple uses/channels both on enterprise and individual levels. The app can be used at home and in healthcare centers by medical professionals. Its applicability to multiple segments and use cases can provide a recurring revenue source.
- 7) Since its commercial launch, PainChek has quickly been accepted by some of Australia's largest residential care centers, such as Allity Aged Care. Given the breadth of aged care centers across globe, an exponential revenue growth opportunity exists for PainChek. Including 21 Residential Aged care clients with annual licenses and more than 6000 clinical assessments during 2018.



- 8) PainChek can be seamlessly integrated with existing healthcare management systems to build a combination that can be marketed as a one-stop platform for complete aged care. Making such an integrated platform available to the existing clients of these system operators provides additional market opportunity for PainChek.
- 9) Co-founders of PainChek are working with the firm, which means that the tool's development will remain consistent. Professor Jeff Hughes is currently the Chief Scientific Officer, while another co-founder, Dr. Kreshnik Hoti, is a Senior Research Scientist. Since his appointment as MD in 2016, Phillip Daffas has overseen the evolution of ePAT and now PainChek as a utility health tool producer. Backing Daffas is a well-qualified board chaired by a technology veteran, John Murray. PainCheck now has sales, marketing and technical support capability as part of the go-to-market team.
- 10) We believe PainChek is currently undervalued. We value the company at 8 cents per share base case and 16 cents per share optimistic case using a DCF-based approach with realistic estimates on care centers outreach and global launch of all possible versions.

#### Key features of the PainChek Dementia app

- Automated facial pain analysis: A 3-second video of the patient's face is recorded through the app, which can recognize 9 micro-facial expressions that indicate pain. This automated process saves time and removes any error caused by human bias.
- Digital questionnaire checklist: This guides the carer through other pain assessment factors, including movement and vocalization. Leading questions are incorporated with yes/no decisions.
- Quantifiable pain assessment score: An overall score is generated based on 42 test points – this sets a global benchmark in pain management.
- Documented electronically via cloud backend: The pain trend line can be observed, along with monitoring of the treatment, and critical medical data is integrated with the patient's medical records.

The PainChek Dementia app is available under enterprise and home care channels. The enterprise solution is sold directly to Residential Aged Care (RAC) and Home Care (HC) operators for dementia patients while the home care solution is sold to the family carers of individual patients for use at home. The technology offers the following key benefits to medical practitioners:

- Understanding the presence of pain when patients are unable to communicate pain and related discomfort.
- Assessing the severity level of pain, whether it is obvious or not.
- Monitoring the impact of treatment to make the overall care process effective.

#### What is unique about PainChek?

Considering that ~20% preverbal children and 80% dementia patients in aged care experience chronic pain, assessing pain accurately becomes the first step toward effective treatment. Although tools to assess pain exist, they are often manual, subjective, and thus used sparingly by carers. PainChek is a secure



Cutting-edge technology with patent protection

smartphone-based medical device that leverages AI to assess and score pain levels in real time, and update medical records on the cloud. Quantifying pain through the use of facial expressions and AI is PainChek's unique proposition, and it is expected to set global benchmarks to assess and test pain.

PainChek is an automated tool and can be used offline. Once downloaded, the app can be used anytime, anywhere. The company holds the license for the facial recognition technology used by PainChek, globally, exclusively and in perpetuity. This gives PainChek total control over the interface, which is Albased. PainChek will be rolled out globally in 2 phases: first for adults who are unable to effectively verbalize their pain, such as people with dementia, and a second version for children who have not yet learnt to speak.

PainChek benefits all key stakeholders and is recognized by leading authorities across the globe (Figure 2).

**Clinical Utility**: It improves the quality of life by reducing patients' need to seek medical advice for pain and enabling better in-home care. It also lowers the rate of incorrectly prescribed antipsychotics.

**Cost Benefit**: PainChek's high speed, ease of use, and instant reproducibility of past records reduce labor time and operational costs for healthcare service providers.

**Quality and Funding:** It provides accurate and effective documentation of pain that supports the accreditation requirements within aged care and assists with accurate classification of residents for Aged Care Funding (ACFI) requirements.

Figure 2: PainChek is recognized by leading authorities (see updated slide 22)











Source: Company

### Milestones for PainChek's regulatory approvals

# PainChek has received TGA and CE clearance and intends to obtain US FDA clearance by 2020

PainChek is the first smartphone-based, pain assessment application to receive regulatory approval for dementia in Australia and Europe. The iOS version of the app was introduced in the Australian and European markets in July 2017. The app received the Therapeutic Goods Administration (TGA) clearance in Australia and Conformité Européene (CE) mark regulatory clearance in Europe as a Class 1 Medical Device<sup>1</sup>. The company presented the iOS version of the app at the Australian Pain Society conference in Adelaide during April 9–12, 2017, in front of 800 pain specialists. It received positive feedback and garnered strong interest from a broad spectrum of potential customers – including large aged-care providers, pain assessment and rehab clinics, and hospital-based anesthetists. The feedback not only endorsed the

With TGA and CE regulatory clearance, PainChek can leverage ~40% of the global market opportunity

<sup>&</sup>lt;sup>1</sup> As per the US FDA, a Class I Medical Device is a device that poses a low-moderate risk to the patient and/or user.



app's potential but also provided PainChek access to a network of pain specialists to support its entry in the Australian market. The company had also conducted multiple validation and implementation studies to endorse the capabilities of this app for regulatory approval. PainChek commenced to commercialize the enterprise version of the app for dementia in Australia in 2018 and plans to enter selected European markets during 2019.

In May 2018, PainChek received a preliminary assessment report from the US FDA regarding its request for PainChek FDA classification as per section 513(g) of the Federal Food, Drug, and Cosmetic Act. The US FDA stated that currently there is no product substantially equivalent to PainChek in the US market. The app, therefore, may be suitable for a risk-based De Novo classification under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act<sup>2</sup>. To support the process, the agency advised PainChek to provide clinical performance data to support its pre-market submission in the US.

In response to this assessment, PainChek disclosed plans to engage with the US FDA to review the currently available PainChek clinical trial results and identify the requirement of any additional data for the De Novo submission, including the need for a clinical trial in the US. In a subsequent update, the company revealed that it is finalizing the US FDA pre-submission documentation as per guidance received from the agency. It also disclosed that although initially the firm had planned to obtain the US FDA regulatory clearance of PainChek in dementia by the end of calendar year 2018, requirement of some additional studies is expected to extend the timeline. Based on this, the company estimates that it will be able to receive PainChek US FDA De Novo clearance in 2020, in line with its US commercial launch projections. With its entry into the US market, the company expects to be able to access 70% of the global market opportunity.

Access to US market by 2019–2020 is expected to open up the opportunity to access 70% of the global market

# Various studies demonstrate validity and reliability of PainChek in dementia

During FY2015–FY2016<sup>3</sup>, PainChek conducted 3 validation studies across accredited RAC facilities in Australia, involving residents with moderate-to-severe dementia that demonstrated a strong correlation with the current Australian gold standard for pain assessment, namely, the paper-based Abbey Pain Scale (APS). Validation testing of the app for dementia was completed in FY2016. The following 3 validation studies have been published:

1) 'Pain Assessment in Dementia: Evaluation of a Point-of-Care Technological Solution': This was an observational study published in the Journal of Alzheimer's Disease in August 2017. In this study, psychometric properties of PainChek were compared with the APS as a point-of-care technological solution. 40 aged-care residents (70% females) aged >60, with moderate-to-severe dementia and a history of pain-related condition(s), were recruited for this study. 353 paired pain assessments (either at rest or post-movement) were recorded and analyzed. The results demonstrated that PainChek has excellent concurrent validity and internal consistency, together with good interrater reliability and discriminant validity. The results also showed that PainChek offers psychometric properties, which make it suitable for use in assessing pain in people with moderate-to-severe dementia. The study confirmed that the dementia

Validation studies evaluated psychometric and clinimetric properties of PainChek

<sup>&</sup>lt;sup>2</sup> The 510(K) De Novo is a process for novel devices whose type has not previously been classified.

<sup>&</sup>lt;sup>3</sup>The company's financial year ends on June 30.



app has additional benefits over the current paper-based technology due to its automated facial expression assessment feature.

- 2) 'Psychometric Evaluation of the Electronic Pain Assessment Tool: An Innovative Instrument for Individuals with Moderate-to-Severe Dementia': This was a 10-week study, published in the journal Dementia and Geriatric Cognitive Disorders in January 2018. The study aimed to investigate the psychometric properties of PainChek compared with the APS. It involved 34 residents aged  $85.5 \pm 6.3$  years, predominantly with severe dementia. 400 paired assessments were performed. The study demonstrated that PainChek is a suitable tool for the assessment of pain in this vulnerable population. Concurrent validity (r = 0.911) and all reliability measures (r = 0.857; intraclass correlation coefficient = r = 0.904; r = 0.950) were excellent, while discriminant validity and predictive validity were good.
- 3) 'Clinimetric Properties of the Electronic Pain Assessment Tool (ePAT) for Aged-Care Residents with Moderate-to-Severe Dementia': In this study, published in the Journal of Pain Research in June 2018, clinimetric properties (clinical utility and predictive validity) of PainChek were evaluated. The study involved 34 residents aged 85.5 ± 6.3 years, predominantly with severe dementia, in 2 RAC facilities in Western Australia. 400 paired assessments were performed. The clinical utility and predictive validity scores were calculated with the APS as a reference. The results were positive and demonstrated high accuracy, sensitivity, and specificity of the app in detecting pain in individuals with dementia. The results also showed the clinical usefulness of PainChek in identifying pain in patients with moderate-to-severe dementia.

Meanwhile, over the past few years, the company has also presented a few studies in many conferences, such as the Australian Pain Society annual scientific meeting. The studies presented include the following:

- 1) 'Evaluation of an Automated Facial Recognition Software Application for Assessment of Pain': The study, presented at the 2015 Australian Pain Society Annual Scientific Meeting, aimed to assess the feasibility of using the facial domain of PainChek for pain management in patients with cognitive dysfunction. The sample size was 43 individuals (22 women and 21 men) aged 54 ± 14 years, with chronic pain. Each participant completed a questionnaire, which was derived from consensus recommendations of international interdisciplinary experts on pain assessment. The questionnaire included self-rating scales for validated measures of pain, such as the Visual Analogue Scale (VAS), the Numerical Rating Scale (NRS), and the Verbal Descriptor Scale (VDS). The study demonstrated that PainChek was able to identify the characteristic facial patterns associated with chronic pain in patients with impaired cognition.
- (ePAT) in Residents with Dementia': The study was presented at the 2016 SHPA National Conference. In this correlational study that aimed to validate PainChek against the APS in residents with moderate-to-severe dementia, the former exhibited a significantly better performance, irrespective of the activity involved during the assessment. The sample size for this study was 40 residents (30% men aged 80 ± 9.1 years, with clinical pain, from 3 aged-care homes) in metropolitan Western Australia. The residents were independently and simultaneously assessed for pain using PainChek and the APS.

Studies have demonstrated a strong correlation between PainCheck and APS in moderate-to-severe dementia



(ePAT) in Residents with Moderate-To-Severe Dementia: A Pilot Study': In this pilot study, presented at 2016 Australian Pain Society Annual Scientific Meeting, PainChek was validated against the APS in residents with dementia. 8 residents (50% men aged 81 ± 11.5 years, with various pain conditions) were recruited from a single aged-care site in Western Australia using purposive sampling. Each resident's pain was independently evaluated using 2 assessment tools during routine care, either at rest or post-movement. The study demonstrated a significant level of correlation between the APS and PainChek while assessing pain in patients with dementia, both at rest and on movement.

# PainChek has conducted implementation studies in dementia to establish clinical utility

PainChek undertook implementation studies with industry partners during FY2016 to test its app's clinical utility in dementia cases and provide data related to its benefits in clinical practice. The company had planned to complete these studies in aged-care homes in Q3 2017, and later disclosed that it had achieved this milestone well ahead of the planned date.

Over October–December 2016, the firm conducted a pilot study to evaluate the reliability of PainChek among raters when assessing pain in people with moderate-to-severe dementia. The study was presented at the 2017 Australian Pain Society Annual Scientific Meeting. For this study, 10 residents (40% men) aged  $81 \pm 11.4$  years were recruited from a single aged-care home in Western Australia using purposive sampling. The ratings were undertaken at rest and in mobilization. Raters were paired to assess pain but were kept unaware of each other's responses. A total of 76 assessments were conducted. The results demonstrated the reliability of PainChek and suggested it as an objective measure of clinical pain in moderate-to-severe dementia.

In the second half of FY2016, an implementation study, Face of Pain in Dementia, was conducted by PainChek in collaboration with researchers from the School of Pharmacy at Curtin University. The results of the study were published in Clinical Interventions in Aging in July 2018. The initiative provided for clinical implementation of the app within 10 RAC homes across regional and metropolitan Victoria. The primary aim of the study was to assess the feasibility and clinical effectiveness of PainChek in assessing pain among residents with moderate-to-severe dementia. The secondary goal was to determine the clinical impact of the use of PainChek in pain management and associated pain-dependent behavioral outcomes, such as agitation and aggression, in residents.

# Validation studies for evaluation of PainChek app in infants are planned

The firm reported that it is progressing well on the development of the PainChek app for infants as well. The software development was reported to be on schedule, and the company expects to initiate testing and validation studies in Australia in the second half of 2019. With these milestones in place, PainChek expects to be able to achieve TGA and CE mark in 2020 and US FDA clearance by 2020.

Implementation studies establish clinical benefits of PainChek app

Validation studies for infant app planned in FY2019

### The competition for PainChek – there is none

There is no competition. Physicians routinely assess pain using various rating scales such as such as the Visual Analogue Scale (VAS), the Numerical Rating Scale (NRS), and the Verbal Descriptor Scale (VDS) we mentioned above. However for people who cannot communicate effectively, there is no solution other than the PainChek app, other than the caregiver watching for pain-related behaviours or other unusual behavior. This gives PainChek a remarkable first-mover advantage<sup>4</sup>.

Theres's no competition on the horizon, either. Any automated pain assessment system that would seek to compete with PainChek would have to out-innovate PainChek's intellectual property<sup>5</sup>, be tested clinically, and then be appropriately branded. With PainChek having worked on all three barriers to entry, that may prove a challenge. Throw in the fact that nViso already have more than 5 million faces within their data base, and the fact that nViso's low power SDK design allows for remote off line testing capability, and those barriers to entry may prove formidable.

### Key addressable markets for PainChek

PainChek is focusing on carers of individuals who are unable to express their pain. The company is targeting the following key markets as an initial opportunity:

- 1) Dementia sufferers: Carers may include healthcare professionals (HCP), general practitioners, family members, etc.
- 2) Preverbal children: Carers may include parents, HCPs, day care workers, baby-sitters, etc.

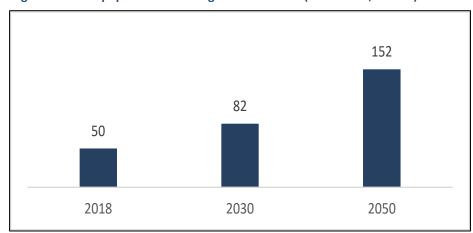


Figure 3: Global population suffering from dementia (2018–2050; million)

Source: World Alzheimer Report 2018

<sup>&</sup>lt;sup>4</sup> BMC Geriatr. 2014 Dec 17;14:138. doi: 10.1186/1471-2318-14-138.

<sup>&</sup>lt;sup>5</sup> See *Pain assessment method and system*, WO/2016/025989, priority date 18 August 2014, invented by Jeff Hughes, Kreshnik Hoti and Mustafa Atee. This patent application has yet to translate into granted US or European patents as yet.



#### Market size of dementia

Globally, 50 million people are suffering from dementia<sup>6</sup>. The number is expected to rise by 3x to reach ~152 million by 2050 (Figure 3). Dementia is currently one of the top 5 major causes of death globally.

Dementia is a collective name for progressive brain syndromes that affect memory, thinking, behavior, and emotion. There are over 200 subtypes of this affliction, including Alzheimer's, vascular dementia, and dementia from Parkinson's disease. Alzheimer's disease accounts for 60–80% of dementia cases.

#### **Dementia in Australia**

As of 2018, an estimated 0.43 million people are living with dementia in Australia. This number is expected to grow at a 2.3% CAGR to reach 1.07 million by 2058 (Figure 4).

Figure 4: Population suffering from dementia - Australia (2018-2058; million)



The total population of people suffering from dementia is expected to triple by 2050

Source: Dementia.org.au

Dementia presents a significant challenge to healthcare and aged care in Australia. The burden is further exacerbated with age – it is known to be more common after the age of 65.

Within Australia, PainChek is targeting dementia patients in the following three market segments:

- Residential aged care (RAC): Most people with moderate to severe dementia stay in RAC. These represent PainChek's initial market focus areas. In excess of 200,000 people live in RAC in Australia<sup>7</sup> and over half of them will have dementia<sup>8</sup>.
- Australia HealthCare Professional (HCP) segment: The segment includes 12,000 Registered GP's, Physio's, and Registered Nurses operating within a range of profit and not for profit entities. These people supply specialist services for people living with dementia within RAC facilities and in the home environment.
- Australia Home Care Operators and Direct to Home Carer segment:
   The segment includes large not-for-profit RAC providers are also
   Home Care Operator (HCO's) providing services and home care

<sup>&</sup>lt;sup>6</sup> Source: World Health Organisation, Dementia Fact Sheet, 12 December 2017.

<sup>&</sup>lt;sup>7</sup> Source: AIHW, Older Australia at a glance (aihw.gov.au).

<sup>8</sup> Source: healthdirect, Dementia statistics (healthdirect.gov.au).

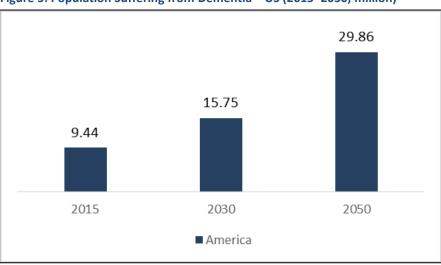


packages for people with dementia who prefer to live at home. Majority of people with dementia in Australia live at home ( $\sim$  300,000) and many of them have access to these HCO packages.

#### **Dementia in America**

The number of people suffering from dementia in the US is expected to grow at a 3-4% CAGR to reach ~30 million by 2050 (Figure 5).

Figure 5: Population Suffering from Dementia – US (2015–2050; million)



In the US, Alzheimer's dementia occurs most commonly in population aged >75 years

Source: Statista.com

Alzheimer's dementia occurs most commonly in population aged >75 years (Figure 6)<sup>9</sup>

<sup>&</sup>lt;sup>9</sup> The total of pie chart may not add to 100% due to rounding off



4% 16% 37% 37% ■ 85+ years ■ 75–84 years ■ 65–74 years ■ <65 years

Figure 6: Population suffering from Alzheimer's dementia - by age (2018)

Source: Alzheimer's Association Report

According to 2018 Alzheimer's Disease Facts and Figures, California recorded the highest number of patients with Alzheimer's dementia, followed by Florida and New York (Figure 7). Moreover, the number of caregivers of Alzeimer's dementia is also significantly high in these cities. The Southeastern and Western regions of the US are expected to experience the highest percentage increase in the number of people with Alzheimer's dementia, due to rise in the population aged 65 and beyond in these regions.

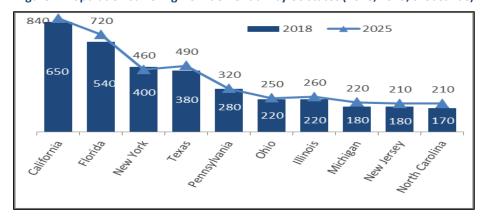


Figure 7: Population suffering from dementia – by US states (2018, 2025; thousands)

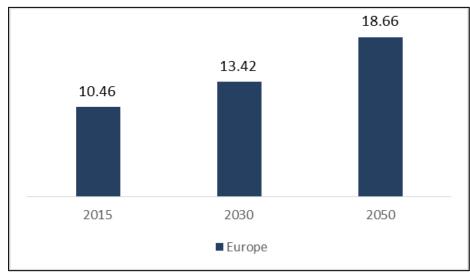
Source: Alzheimer's Association Report

#### **Dementia in Europe**

The number of people suffering from dementia in Europe is expected to grow at a 1.67% CAGR to reach  $^{\sim}19$  million by 2050 (Figure 8).



Figure 8: Population suffering from dementia – Europe (2015–2050; million)

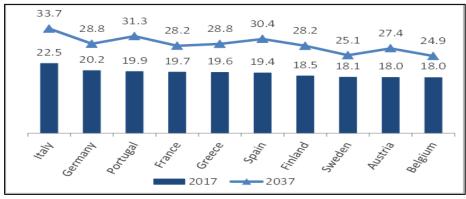


In Europe, Italy has the highest number of dementia cases

Source: Statista.com

Among European nations, Italy has the highest number of people with dementia – 22.5 per 1,000 of population (Figure 9). This figure is expected to grow at a 2.04% CAGR and reach 33.7 per 1,000 of population by 2037. Italy is closely followed by Germany, Portugal, France, Greece, and Spain.

Figure 9: Population suffering from dementia – by country (2017, 2037; per 1,000 of population)



Number of people suffering from dementia in Europe expected to reach 18.66 million by 2050

Source: OECD

In the US, the prevalence rate of pain in the population suffering from dementia was 83% in 2017. The same is the case in Europe, with studies reporting that 40–80% of people with dementia suffer pain. This trend is continuous across Europe, with pain reported in 32%, 43%, and 57% of people with dementia in Italy, the Netherlands, and Finland, respectively.

In our opinion, the high prevalence rate and scarce availability of products comparable to PainChek offer considerable opportunities in the US and European markets for pain management in dementia.



141 million births per year in the world serve as high potential market for PainChek

#### **Preverbal market**

The preverbal population, which includes neonates, infants, and toddlers, comprises children who have not started to speak. According to the World Bank, the total estimated number of births in 2016 was ~141 million. The birth rate (per 1,000 of population) has decreased by 0.83% from 2010 to 2016, which was offset by the population growth rate of 1.19% over the same period. The combined neonatal market share (in terms of new births) of the US, EU, and Australia is around 6.6% (Figure 10). Despite the low percentage, these countries spend more on neonatal healthcare.

There are 400 Million children between ages 0-3 years in total, which is the core mrket opportunity. PainChek Kids has hospital-based opportunities (around 5-10% of the market) but the largest will be for parents at home needing to make a general assessment of their child's well being. The good comparator here is the the thermometer – all parents have one at home for their children – so will be the case for PainChek during these pre-verbal years.

2.8% 3.6% 0.2% 0.2% 93.4% • US • EU • Australia • Others

Figure 10: Global Neonatal Market Share - by country (2016)

Source: CDC, Australian Bureau of Statistics, Statista.com, World Bank

In the preverbal population, pain assessment remains misunderstood, under diagnosed, and also leads to undertreated/untreated medical problems. Up to 40% of children and adolescents complain of pain that occurs at least once weekly, with a minimum of 15–20% of children suffering from chronic pain. Additionally, every year, ~1.5 million children have surgery; of these children, many receive inadequate pain relief, resulting in pain becoming chronic in ~20% cases.



Demand from aged care sector is expected to continue to rise

#### **Commercialization Strategies**

# PainChek benefits from the growth of Australian aged care sector, and the current Royal Commission

The Australian aged care sector offers care in 2 settings – home care services and residential aged care services. In the former case, care is provided for people living at home, while in the latter setting, care is provided at residential facilities. Many reports suggest that the aged care sector in Australia is expected to grow significantly over the next few years. According to Treasury's 2015 Intergenerational Report, the number of Australians aged 65 and above is forecast to more than double by 2054–2055, increasing from ~3.6 million in 2014–2015 to ~8.9 million in 2054–2055. The trend is consistent with estimates from the Aged Care Financing Authority (ACFA), which predicts that 76,000 new residential aged care places will be required by 2023–2024 to meet the continued demand.

Recently, the Australian government enhanced focus on the aged care sector by establishing the Royal Commission within the sector<sup>10</sup>. Funding for aged care is at record levels. According to the ministry of Australia, in 2017–2018 alone, aged care spending was estimated at A\$18.6bn. Over the next 5 years, funding is expected to grow by A\$5bn to reach A\$23.6bn. The government provides more than A\$50m each year for dementia-specific programs. Moreover, a further A\$5.3m has been committed by the government over the next 4 years to pilot improvements to care for people living with dementia, including focus on use of innovative technologies.

It is estimated that up to 80% of aged care residents experience chronic pain<sup>11</sup>. Moreover, >50% of people in Australian aged care centers have dementia<sup>12</sup>, while 67% require high-level care to manage behavior. This suggests that a considerably high proportion of people with chronic pain also have cognitive or communicative impairment and inability to report pain. Meanwhile, according to Painaustralia – Australia's pain advocacy body – a number of media reports in 2017–2018 suggested inferior quality of care in the aged care sector, including barriers to timely and appropriate pain management services. These observations suggest that there is a stark need for improvement in pain assessment solutions in the aged care setting.

The focus of the Royal
Commission on improving care
for dementia patients in aged
care sector bodes well for
PainChek

With establishment of a Royal Commission for the aged care sector and government's focus on introducing innovative technologies for dementia patients, it is expected that the commission would undertake measures to improve pain management. The commissioners are required to provide an interim report by October 31, 2019, and a final report by April 30, 2020. We believe that Royal Commission reports could provide significant growth benefits to PainChek by recommending adoption of a holistic multidisciplinary approach to pain assessment in the aged care sector.

<sup>10</sup> The Royal Commission into Aged Care Quality and Safety was established on October 8, 2018 by the Governor-General of the Commonwealth of Australia

<sup>&</sup>lt;sup>11</sup> Aged Care Awareness

<sup>&</sup>lt;sup>12</sup> Australian Govt. Dept. of Health data as of June 30, 2015



# PainChek will globally commercialize different versions of the app by 2019–2020

PainChek's commercial strategy revolves around the establishment of PainChek as a cost-effective solution to carers of people who cannot verbalize their pain, typically those suffering from dementia. Given the multiple use cases for the PainChek tool, the company offers it as a Software-as-a-Service (SaaS) platform. It is being sold via software enterprise partners and direct to businesses. It will also be offered directly to consumers via App Store and Google Play. Considering the different user bases (patients, guardians, and carers), various solutions have been customized (Figure 11):

#### Enterprise Solutions

- These solutions are offered directly to RACs and home carer operators. Commercially, they benefit both the company and RACs. With a consistent influx of dementia patients, this tool provides high utility at minimal pricing, simultaneously acting as a recurring revenue source for the company. Painchek is now beginning to offer these solutions to GPs, physiotherapists and other Allied Health providers.
- PainChek has built a cost-effective enterprise solution with well-established operational functions – pre-sales, on-boarding, and post-sales. It provides on-site demonstrations and, if required, offers 4–6 weeks of product trials. It establishes a recurring monthly subscription based on the number of beds/residents. It supports care centers with on-site clinical training and online video training tools. Post-sales support includes follow-up training (if required).
- The typical sales cycle (post successful product trial) ranges from 1–4 weeks, with some large centers often taking up to months to conclude the commercial negotiation. License agreements with healthcare centers are usually signed for 1–3 years.

#### o Home Care Channel

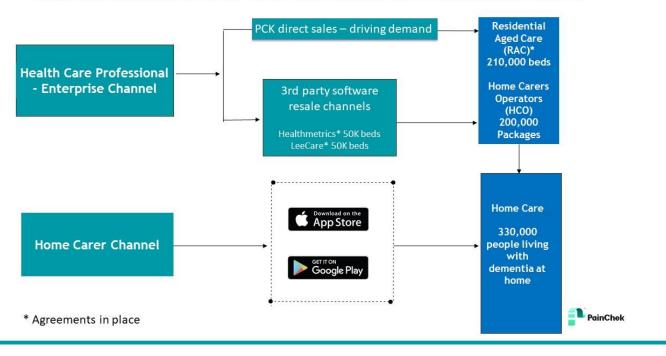
A lot like the home glucose monitoring system, PainChek's home care solutions can be used at home by relatives of dementia patients or guardians of preverbal children. This tool can also be used by pharmacies for their clients (on need basis).

The enterprise version of the PainChek app has already been commercialized in the Australian market for residential care. Meanwhile, the company launched the 'shared care' app version in November 2018 and the PainChek Direct to Home Carer option is expected to follow in 2019 (Figure 12). We lok into shared care and Direct to Home Carer in more detail below.



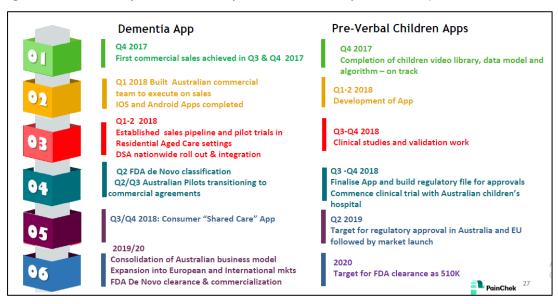
Figure 11: PainChek's Australian business model

#### PainChek® Australian RAC and Home Care business model



Source: Company

Figure 12: PainChek Key Milestones, as it presented them in September 2018)



Source: Company



Figure 13: PainChek's International Expansion Strategy (as of September 2018)



Source: Company

PainChek plans to leverage learnings from US FDA submission of clinical data on dementia for children's app clearance in the US

Besides focusing on developing different versions of the dementia app, the company is evaluating international expansion. With CE and TGA approval already in place, PainChek claims to already have access to 30–40% of the global market opportunity in dementia. The company is also developing PainChek as a tool for preverbal children. Commercial milestones for the preverbal children app include undertaking clinical and validation studies in Q3–Q4 2018, targeting regulatory approval in the EU and Australia by Q2 2019. At the same time, PainChek expects to obtain de novo clearance for the dementia app in the US based on additional clinical studies in 2019/2020. Learnings from the US FDA clearance of the dementia app are expected to be leveraged to develop and build US FDA clinical data for the preverbal children app (US FDA clearance targeted by 2020) (Figure 13).

# PainChek is likely to continue to benefit from growing client base and software partnerships

PainChek has been extending its dementia app to all major care centers engaged in palliative care and general practitioners (GPs). The app is also been marketed to be used by pharmacies and under home care settings. As of September 30, 2018, the company had 16 clients (including Dementia Support Australia) with one-year subscription agreements in place, with a monthly recurring revenue (MRR) of A\$10,600, which equates to an annualized recurring revenue (ARR) of A\$127,000. The client base includes 15 RAC clients across 20 RAC facilities as of 30 September 2018 – up from 5 clients across 5 RAC facilities as of 30 June 2018 (Figure 14 and Figure 15):

As of September 2018, PainChek has signed contracts with 15 RAC clients



Figure 14: RAC Agreements (2017-2018)

Summary of RAC agreements over time	No. of Customers	No. of RAC's	No. of Licensed Beds
Number signed in the 6 months ended 31 March	2	2	65
Number signed in the 3 months ended 30 June	3	3	273
Number signed in the 3 months ended 30 Sept	10	15	1165
Total	15	20	1503

Source: Company

Figure 15: Strong association with multiple care centers across Australia



Source: Company

In June 2018, the company rolled out the PainChek app to 150 consultants of Dementia Support Australia (DSA) after a pilot study conducted during September 2017–April 2018 confirmed improvement in behavioral problems of clients with dementia. The app was initially rolled out in Western and Southern Australia, before being rolled out across the eastern Australian states.

To ensure customer loyalty and smooth client relationships, PainChek has also developed standard operating procedures for onboarding and training new clients and started tracking monthly satisfaction levels and effective use of the PainChek app for existing customers through the Net Promoter Score<sup>13</sup>.

Recently, PainChek signed software integration agreements with Health Metrics and Leecare Solutions – software solution providers to health and aged care markets. The collaborations are expected to provide PainChek outreach across residential aged care centers and retirement homes across Australia and overseas.

Health Metrics is the leading care management system (CMS) provider across Australia. Its end-to-end enterprise system, eCase, supports the functions of retirement villages, residential aged care, and home care centers. Its software solutions are designed to document clinical data and improve the efficiency of operations of healthcare providers. The platform caters to all the automation and documentation needs of the aged care market. The PainChek app will

PainChek advances its offerings through various software integration agreements

<sup>13</sup> This is a management tool that can be used to gauge the loyalty of a firm's customer relationships



- be integrated with the eCase platform. This integrated service will be co-promoted to healthcare providers and caregivers, commencing with the Australian residential aged care sector. PainChek and eCase's integration was completed during Q2 2018.
- Leecare Solutions is a market leader in care management software solutions to the health and aged care markets across Australia and overseas. Powered by proprietary intelligent design concepts, Leecare's Platinum 5.0 platform is a web-browser-based, clinical, care, and lifestyle management application for the aged and community care industry. Integration of PainChek's assessment tool with the Platinum 5.0 platform, expected early in 2019, will provide RAC clients and healthcare professionals with the benefits of a fully integrated and automated care management system. The 2 companies will co-market the benefits of the collaboration to Leecare's existing clients.

These software integration agreements are expected to allow PainChek to fully automate pain assessment testing for more than 100,000 approved places/beds (representing ~50% of the Australian aged care market) and gain access to international markets where these integration partners have overseas presence. PainChek argues that its API makes software integration a fairly straightforward process

Patient/Resident
Care System

Integration Component (bespoke)

PainChek API
Provides secure, authenticated and controlled access to PainChek data

Figure 16: The PainChek API has been designed to be easy to integrate into client systems

Source: Company

PainChek has also inked deals/licensing agreements with various technology/third-party software providers to advance the applications of PainChek. These include the following:

• **nViso**: PainChek acquired the global, exclusive, and perpetual license for use of nViso's Al-based market-leading facial emotion technology in the



field of pain assessment. PainChek can also fast-track new developments through its in-house software development team and data scientists. In the process, nViso bought an equity stake and became a shareholder, and no royalty payments are required be paid to nViso on future sales revenues. This exclusive license allows PainChek to use the technology without any disruption, patent filing, and disclosure of technological specifications. In addition, no royalty payment means PainChek is aloof from any major financial strain on operational cash flow.

 Darwin Digital Designs: It supported PainChek in developing the dementia app and backend systems. This has helped the possibility of integrating the tool with any care system, seamless use of the tool by professionals, and use in home settings.

#### **Other Commercialization Measures**

The company has also undertaken other strategies to commercialize the PainChek app:

- To support the commercialization drive, PainChek built an initial core sales and support team.
- The company has also onboarded founders Professor Jeff Hughes as Chief Scientific Officer and Mustafa Atee as Senior Clinical Research Scientist. This keeps the tool development process seamless, transparent, and continuous. Recently, Dr. Jennifer Abbey – developer and innovator behind the Abbey Pain Scale – joined the PainChek clinical advisory board. With knowledge and experience in developing the standard pain assessment tool, Dr. Abbey is expected to help the company expand clinical indications for PainChek.
- PainChek has also submitted national patent filings for the PainChek app in all key global markets, including Europe, the US, Australia, China, and Japan.

### **Key Business Opportunities**

# PainChek's initial focus is on dementia patients within RAC setting in Australia and preverbal children

Opportunities where PainChek has already made significant progress include people living with dementia (sufferers and carers) in the RAC setting. Australia comprises 950 RAC operators who manage a total of 2,700 RAC's with 210,000 resident beds. Of the ~400,000 people living with dementia in Australia, 115,000 are within RAC sector. The monthly Average Revenue per Licensed Bed (ARLB) from RAC customers is A\$5/month, and the Average Revenue per Active Resident is ~A\$10/month, based on actual resident usage. As of September 2018, the company has penetrated 1.5% of the potential Australian Aged Care market.

For pre-verbal children, the company plans to conduct validation studies in late FY2018 and plans to launch it in Australian and European markets during 2019.

PainChek's Average Revenue per Active Resident is approximately A\$10/month



#### PainChek plans to launch new PainChek shared care version

After launching the enterprise version for RAC setting in Australia in 2017, the company has now entered the shared care/consumer segments (Figure 17). The company has also finalized a series of PainChek training videos developed with Dementia Training Australia. With the availability of 'shared care' version of the app and training videos, HCOs and other HCP groups will be able to provide access to PainChek to family carers (only through shared care license). With its shared care application, the company plans to integrate pain management for ~300,000 dementia patients in Australia who prefer to live at home. The strategy seems to be driven by the increasing preference of patients, who have comparatively less severe dementia, to exercise their option of staying at home and Australian government's homecare-related reforms, notably 'consumer directed care initiative' and 'Increasing Choice in Home Care' measure announced in 2015<sup>14</sup>. Over time, as the 'shared care' app becomes more widely used and accepted by healthcare professionals, the company plans to enable all home carers to license Painchek directly. Besides Australia, the company is expected to benefit from this strategy even in international markets. In the US, for instance, aging baby boomers are shifting their preference from nursing homes to home or community-based care.

PainChek® portfolio transcends the Dementia Journey

HCP Carers

Care Environment

Consumer / Carer

Dementia Stage

Onset Dementia

PainChek® Staged entry

PainChek® staged entry

Figure 17: PainChek explores different dementia settings

Source: Company

#### PainChek plans to explore other markets

Besides dementia, PainChek may also explore the utility of its offerings in other nonverbal adult populations such as those with other neurodegenerative disorders, intellectual disabilities, traumatic brain injuries,

<sup>&</sup>lt;sup>14</sup> In 'consumer directed care' initiative, on July 1, 2015, it became mandatory for all home care packages to be delivered on a consumer directed care basis; within 'Increasing Choice in Home Care' measure, the government announced multiple reforms including providing improved access to home services and allowing older Australians to choose who provides their care.



PainChek may also explore market opportunities beyond dementia and paediatric care including cognitive impairment and palliative care aphasia, those receiving palliative care, and post stroke patients. In fact, the company plans to target a broader set of population with cognitive impairment. One tool commonly used to manage pain in such patients is the PAINAD scale. However, the tool cannot provide a verbal report of pain, and so its intensity cannot be determined. The market of Delirium – a frequent form of cognitive impairment among older adults – is expected to grow at a 6% CAGR during 2016–2023 providing a significant market opportunity for PainChek in this patient population.

We believe that palliative care is another lucrative segment for PainChek. Palliative care patients who also suffer from pain are often unable to self-report their pain, placing them at increased risk for under-recognized and undertreated pain. Therefore, use of appropriate pain assessment tools significantly enhances the likelihood of effective pain management and improved pain-related outcomes. Also, the market opportunity associated with palliative care is quite high. In the US, the prevalence of hospitals (50 or more beds) with a palliative care team grew at a CAGR of 6.6%, reaching 1,831 over 2000–2016.

PainChek may also find potential use in intensive care unit (ICU) patients. In most cases, patients admitted to an ICU are the ones who have suffered from severe trauma, undergone major surgery or been treated for a serious medical illness. Although these patients often experience more intense pain than general ward patients, they are frequently unable to communicate their experiences to health care providers, thus preventing accurate assessment and treatment of their pain. The problem is further exaggerated in intubated adults and mechanically ventilated patients. It is estimated that accurate assessment of pain is made in less than 40% of total mechanically ventilated patients. Since pain is quite subjective, the accurate assessment of pain is very difficult. In our view, PainChek can, therefore, be leveraged for pain assessment in these critically ill patients.

Besides these opportunities, another important business opportunity lies in the deaf and mute patient population, who by definition struggle to verbalise their pain levels. It is common for people with hearing disabilities to encounter troubles with medical care. In case of hospitalization or pain, it is difficult for such people to describe their condition due to the lack of adequate sign-language interpreters and inability to effectively communicate with medical staff. The problem is further exacerbated when patients who have both speech and hearing disabilities need to undergo surgical procedures and require special preparation and care.

### PainChek has potential to become a standard of care

# PainChek's market opportunity is comparable to basic diabetes management tools

According to Alzheimer Disease International, ~50 million people were estimated to be suffering from dementia in 2017. The number is expected to double every 20 years and become almost thrice the current figure in 2050, reaching 131.5 million. Considering that the annual cost of using PainChek per



PainChek's market opportunity is comparable to home-based tools such glucose monitoring strips for diabetes management

resident is A\$120 or US\$85<sup>15</sup> (at A\$10 per month per resident), the total market opportunity comes out to be A\$6bn per year or US\$4.25bn per year for dementia patients. As the PainChek app also targets carers of dementia patients, estimated to be thrice the number of dementia patients in major markets (Figure 18), the opportunity for PainChek grows even further. With such an enormous market opportunity, PainChek's potential to become a standard of care is comparable with other basic tools such as glucose monitoring strips for diabetes management. Multiple reports claim that the global blood glucose test strips market was valued at US\$8–10bn in 2017. Also, as per the World Health Organization, 425 million people are living with diabetes at present, and this number is expected to increase to 625 million by 2045. Based on these estimates, it seems that the dementia market is anticipated to grow faster than the diabetes market, thus pointing toward an even greater market opportunity for PainChek in the next few years.

6,000,000 people living with 7,500,000 dementia people living with dementia<sup>1</sup> US 18,000,000 carers of people with dementias 400,000 people 6,500,000 health care living with professionals who could use dementia<sup>2</sup> PainChek<sup>6</sup> EU 22,500,000 carers of People with dementia5 Australia 8.000.000 health care 1,200,000 carers of professionals who could use PainChek<sup>6</sup> People with dementia3 500,000 health care professionals who could use PainChek4

Figure 18: PainChek targets people living with dementia and its carers

Source: Company

# PainChek offers multiple advantages over currently used pain assessment tools

As clinical assessments that use the PainChek app for dementia continue to grow — 4,800 assessments had been completed as of September 2018, shooting up from 1,250 assessments in June 2018 — PainChek is being perceived as a pain 'thought leader'. The company's clinical data has been globally recognized, along with support from prominent government bodies such as Dementia Support Australia, Dementia Training Australia, and Pain Australia. Such market recognition in a short time period indicates that PainChek has the potential to become a standard for pain assessment in clinical care.

<sup>&</sup>lt;sup>15</sup> All currency conversions are at US\$ 1 = A\$ 1.41265 as of October 25, 2018



PainChek's advantages over currently used pain assessment tools indicate its potential to become standard of care In the past decades, many pain assessment tools have been used to quantify pain in dementia (Figure 19). In 2002, AGS panel sought to define pain behaviors in elderly people with cognitive impairment through 6 domains facial expression, negative vocalization, body language, changes in activity patterns, changes in interpersonal interactions, and mental status changes. However, due to considerable overlap of these behaviors with other common behavioral symptoms or cognitive deficits, the assessment was sometimes observed to be confounded. A few studies have also indicated the limitations of other pain assessment tools that were in use over the past few years. In one of these studies, Lichtner et al. conducted an evaluation of 28 pain assessment tools – including PAINAD and APS – developed subsequent to the AGS panel. However, researchers found that in the absence of studies involving psychometric properties of these tools, none of the tools can be recommended based on reliability, validity, feasibility, or clinical utility<sup>16</sup>. Meanwhile, PainChek's validation studies recommend use of this tool based on psychometric and clinimetric evidence. Also, in validation studies involving patients from RAC facilities in Australia, the app has already shown strong correlation with the current Australian gold standard for pain assessment — APS - in patients with dementia. Moreover, being an electronic pain assessment tool, PainChek has considerable advantages over other paperbased tools as it eliminates bias while interpreting pain. The evidences indicate the significant edge PainChek has to become a standard of care in evaluating pain in patients with cognitive impairment and/or dementia.

Figure 19: Evolution of Pain Assessment in Dementia

Source: Company

<sup>16</sup> Valentina et al., Pain assessment for people with dementia: a systematic review of systematic reviews of pain assessment tools, Volume 14, 2014, Page 138.



#### PainChek's solid leadership team

We believe PainChek has a leadership team that can create significant shareholder value from Jeff Hughes' original work.

**CEO Philip Daffas** brings a solid global background in diagnostics and medical devices, including successful stints with Cochlear initially as their European Sales and Marketing Manager based in London and VP Global Marketing based in Sydney. Philip was also the European Marketing Director, based in Germany, for the Boehringer Mannheim (now Roche Diagnostics) Diabetes Care business. Daffas often cites glucose monitoring solutions like the Accu-Chek system he and his team marketed at Boehringer Mannheim as an example of how a product like PainChek can mainstream and he brings in the experience and capability to globalize the PainChek business.

**CSO Professor Jeff Hughes**, who led the development of the PainChek app at Curtin University, brings technical smarts highly relevant to PainChek as a company with its plans for new applications of PainChek such as the pediatric application.

The PainChek board, which includes Daffas, has a range of skills relevant to building a company at PainChek's stage of development. Chairman John Murray, whose background is private equity and venture capital. Ross Harricks has a background in medical device development while Adam Davey brings public capital market skills.

#### **Valuing PainChek**

We value PainChek at at 8 cents per share base case and 16 cents per share optimistic case using a DCF approach.

Table 1: Our valuation of PainChek

	Base	Optim.
Value of PainChek ePAT	84.0	165.3
Value of tax losses	-4.1	-4.1
Corporate overhead	-7.7	-7.7
Cash now (A\$m)	2.6	2.6
Cash to be raised (A\$m)	0.0	0.0
Option exercises (A\$m)	4.0	4.0
Total value (A\$m)	78.7	160.0
Total diluted shares (million)	1,014.8	1,014.8
Value per share	\$0.078	\$0.158
Valuation midpoint	\$0.118	
Share price now (A\$ per share)	\$0.044	
Upside to midpoint	168.2%	

Source: Company

**Time horizon:** We constructed base and optimistic case DCFs with a 15 year time horizon.



**Discount rate:** We used a ~11% discount rate to reflect the relatively low risk of PainChek compared to other Life Science ventures<sup>17</sup>

Initial patient numbers: We assume, for conservatism's sake, that for the next five years or so PainChek remains a niche product in its core markets. This still sees steady increases in the average number of treated patients to ~280,000 by FY23 (Figure 20), which at A\$5/month/subject would generate ~A\$17m p.a. 280,000 would represent 2% of the immediate addressable market for PainChek, which is the ~14 million people currently living with dementia in the US, the EU and Australia. Diffusion Theory would suggest 2-3% as the appropriate payoff for usage by innovators of a successful product in the fields being targeted 18. We used A\$5/month since PainChek has previously used this number to describe Average Revenue per Licensed Bed across a range of its RAC customers in Australia 19.

**Operating costs**. We assume that PainChek's current cost base after corporate expenses is A\$2m pa. and will grow by 15% p.a. over the next five years as the company grows its sales tream to roll out the PainChek app globally.

Corporate costs. We assume A\$1.2m in corporate costs p.a.

**Gross margins.** We assume that PainChek can generate gross margins in the order of 85% given the ease with which app-based diagnostics can scale. We see upside to this number based on the fact that sometimes PainChek has to pay away some gross margin to system integration partners.

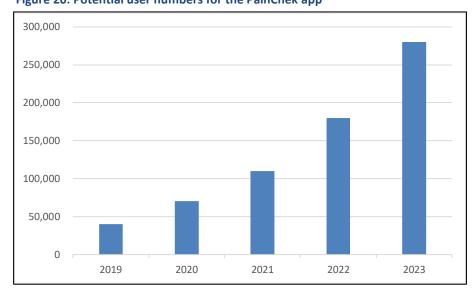


Figure 20: Potential user numbers for the PainChek app

Source: Pitt Street Research

<sup>&</sup>lt;sup>17</sup> For a relevant discount rate, we use varying WACCs depending on the risk for Life Science companies. We start with an RFR of the Australian ten year bond rate and an ungeared beta of 1.1 but use a variable MRP of 7.5%-11.5% (7.5% for 'medium risk' companies, 9.5% for 'high risk' companies and 11.5% for 'speculative' companies). We regard Life Science companies with existing businesses, or who have enough capital to reach the market with their products, as 'Medium' risk. Companies that have small revenue streams from marketed products but that are still potentially in need of capital are 'High' risk. Everything else is 'Speculative'.

<sup>&</sup>lt;sup>18</sup> See Diffusion of Innovations, 5th Edition by Everett M. Rogers (New York, Simon & Schuster, 2003).

<sup>&</sup>lt;sup>19</sup> See, for example, the PainChek investor update of 31 July 2018.



**Software licensing.** We include no value for any royalties on the PainChek app, since PainChek has paid for its SDK in full. We assume no royalties payable to other third party software providers going forward.

#### For the ten years beyond FY23 we used the following assumptions

Table 2: Growth assumptions from FY23

	BASE	OPTIMISTIC
Sales at year 5	16.8	16.8
Growth rate year 6	15.0%	25.0%
Growth rate year 14	5.0%	15.0%
Initial gross margin from year 6	85.0%	90.0%
Initial expenses (% of sales) at year 6	25.0%	20.0%
Margin improvement factor	0.1%	0.1%
Capex (% of sales)	5.0%	4.0%
Ongoing tax rate	30.0%	30.0%
Amount set aside to working capital		
(% of revenues)	5.0%	4.0%
Terminal growth rate	3.0%	3.0%
Terminal margins	35.0%	40.0%

. Source: Pitt Street Research

**Long-run usage potential**. Our assumptions on long run sales growth suggests that the user base of the PainChek app is between 0.6 million and 1.4 million patients.

**Terminal margins.** The potentially high margin nature of the PainChek app suggests that EBITDA margins for the company as a whole could be north of 50% or 60%. We assume that other diagnostic modalities emerge between now and the 2030s which could slightly erode PainChek's competitive advantage and thereby dampen margins.

We see upside risk to our current valuation. Obviously PainChek is at the early stage of its growth. We believe that solid growth in assessment numbers in FY19 will help determine the validity of the valuation range we have developed.

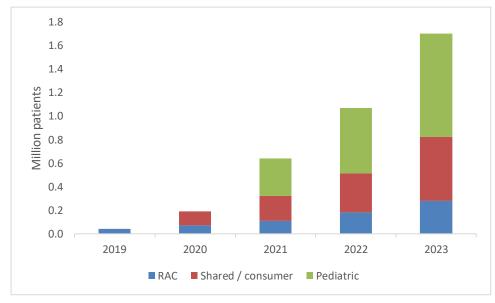
There are, potentially, multiple growth curves. The above valuation depends in large measure on PainChek's early success in growing usage in Residential Aged Care. There are, however, two other growth curves that can potentially layer onto this one.

- **Growth Curve 1: Shared care and consumer for dementia = 3x.**These applications of PainChek can serve a market potentially 3 times the size of the RAC market depending on the geography being targeted.
- **Growth Curve 2 Pediatric users = 8x**. This is a seriously large opportunity. If there are 50 million people with dementia globally, there are 400 million children under 3.



Obviously PainChek has to complete development of the relevant software and start to market the applications, but the 3x and 8x market opportunity suggests a much more aggressive growth profile than the one we have used

Figure 21: One potential chart of PainChek patient numbers should all applications gain a good market response



Source: Pitt Street Research

### Companies to watch

We note nine companies that are comparable to PainChek in the digital health technologies space.

**Reliq Health Technologies** (TSXV:RHT). This company develops and operates mobile software solutions for the community care market. It offers iUGO Health technology platform, a hardware and software solution that allows complex patients to receive care at home.

**ResApp Health Limited** (ASX:RAP). This company develops health care solutions for respiratory diseases. It is developing ResAppDx app for the diagnosis of respiratory disease in infants and children using cough sounds.

**G Medical Innovations Holdings** (ASX:GMV). This company develops mobile technologies to monitor, manage, and enhance clinical and personal health outcomes. It develops Medical Smartphone Case, a solution that turns a phone into a mobile medical monitoring device; and G Medical Patch, a solution that provides continuous and real-time monitoring of a range of vital signs and biometrics.

**Cambridge Cognition** (AIM:COG). This company specializes in the precise measurement of clinical outcomes in neurological disorders worldwide. It offers CANTAB Mobile, a screening tool to identify the earliest signs of clinically relevant memory impairment indicative of Alzheimer's disease; and



CANTAB Insight, an analytical assessment tool that measures brain function and cognitive health across various domains.

**Eyecarrot Innovations** (TSXV:EYC). This company develops products for diagnosing and remediating visual perception disorders. The company's products include Binovi Pro, which allows clinicians to manage various aspects of vision therapy practice; Binovi Coach, a mobile app to allow patients to access doctor-led therapy; and Binovi Touch, a tool for vision training and vision therapy.

**Adherium** (ASX:ADR). This company develops, manufactures, and supplies digital health technologies that address medication use in chronic diseases. It offers Smartinhaler, an asthma and chronic obstructive pulmonary disorder (COPD) medication adherence solution and a mobile app, which provides real time reporting, monitoring, storing, and analysis of inhaler use.

**Kontigo Care** (OM:KONT). This company provides health care solutions for addiction treatment in Sweden. It offers TripleA, a medical device for the treatment and investigation of the harmful use of alcohol; and TripleG, an ehealth system for the treatment and prevention of gaming addiction.

**Cytta Corp.** (OTCPK:CYCA). It collects data generated by home-based medical monitoring devices, such as blood pressure, scale, blood glucose, and pulse oxygen by utilizing Bluetooth connectivity through WiFi and an unlocked Android smartphone. The collected data is transmitted to various electronic medical record platforms through satellite connectivity.

**Lifespot Health** (ASX:LSH). It is developing the BodyTel System that assists with the measurement of functions and indicators related to chronic diseases, as well as monitoring of prescribed therapies for chronic diseases.

Figure 22: Comparable companies for PainChek

			_	
			Market cap	
Company	Location	Code	(USDm)	Web
G Medical Innovations	Rehovot, Israel	ASX: GMV	74	www.gmedinnovations.com
Resapp Health	Perth, Australia	ASX: RAP	56	www.resapphealth.com.au
Reliq Health Technologies	Vancouver, BC	TSX-V: RHT	23	www.reliqhealth.com
Cambridge Cognition	Bottisham, UK	LSE: COG	27	www.cambridgecognition.com
Eyecarrot Innovations	Oakville, On.	TSX-V: EYC	14	www.eyecarrot.com
Kontigo Care	Uppsala, Sweden	Nasdaq OMX Stockh	n 9	www.kontigocare.com
Adherium	Auckland, New Zealand	ASX: ADR	6	www.adherium.com
Lifespot Health	Melbourne, Australia	ASX: LSH	4	www.lifespot-health.com
Cytta	San Ramon, Ca	OTCBB: CYCA	3	www.cytta.com
PainChek			27.2	

Source: Pitt Street Research

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