ASX ANNOUNCEMENT
30 October 2024

30 September 2024 Quarterly Update and Appendix 4C

Positive validation study results pave way for FDA De Novo submission as PainChek delivers 100,000 commercial licences and Infant App launch milestones

PainChek Ltd (ASX: PCK) ("PainChek" or "the Company"), developer of the world's first smart device-based pain assessment and monitoring application, is pleased to announce its quarterly activities and cashflow report (Appendix 4C) for the quarter ended 30 September 2024.

Highlights

- US FDA De Novo regulatory submission in process following successful clinical validation study.
- 100,000 contracted licences with an ARR of $4.8M once fully implemented – 6% increase in licences on the prior quarter and 30% increase on prior year.
- UK contracted licences reach 39,000 – 8% market penetration, a 9% increase in the quarter and 103% over prior year.
- ~62,000 ANZ contracted licences maintaining a ~30% market penetration within aged care, a 3% increase in the quarter and a 6% increase over prior year.
- Retention rate for implemented licenses of 85% for the quarter.
- PainChek® Infant Early Access Program launched in Australia with active users recruited and Infant App approved for launch on Apple iStore.
- Cumulative PainChek pain assessments reaches 7,440,000 – 116% increase over the previous year.
- Customer receipts for the quarter of $912,000.

Commentary

Philip Daffas, PainChek CEO, commented:

"The Company has now achieved three significant milestones.

The first milestone is the achievement of 100,000 contracted global licences across Australia, New Zealand, UK and Canada reflecting an ARR of $4.8M which, once fully implemented, takes the Company to an operational break even position, excluding R&D, corporate and expansion costs. While the majority of these licences are in the aged care sector, they now include new home care and hospital sales, further validating the broad market opportunities for the Company.

In addition, we have now successfully completed the FDA de Novo clinical validation study and are submitting the results to the FDA in November 2024 for US marketing clearance. The US market is the largest healthcare market in the world and the PainChek North American aged care market is estimated to be worth $100M USD per annum.

ABN 21 146 035 127
401, 35 Lime Street,
Sydney, NSW, 2000
E: info@painchek.com
W: painchek.com

These two milestones along with established international market presence and more than 30 partnerships in Australia, NZ, UK, and North America provides the Company with multiple market expansion options within the Aged Care, Home Care and Hospitals markets. We are working with our existing and future partners to expand our business globally in an effective and efficient manner.

We are also pleased to confirm the market introduction of the PainChek Infant technology, initially in Australia, through an early access programme (EAP) directed to parents of infants aged between 1 month to 12 months of age. The goal of the EAP is to finalise the market entry strategy and pricing prior to broader market entry in Q1 2025. The Infant market potentially dwarfs the aged care market as there are 150 Million children born each year and the majority to first time parents.

and the majority to first time parents

The Company is well positioned on all fronts. We continue to establish the PainChek technology as a unique, differentiated and value added offering for our clients."

Core market expansion and market penetration

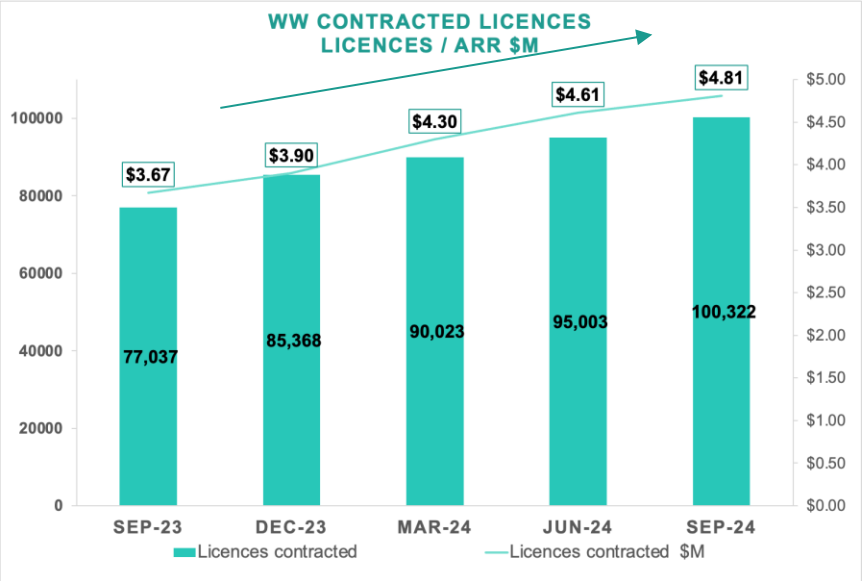
PainChek now has 100,000 contracted licences globally across almost 1,840 aged care facilities, with an ARR of $4.8M once the licences are fully implemented, representing a 6% increase on the prior quarter licences and 30% increase on prior year. ARR (once implemented on these contracted licences) increased 4% in the quarter.

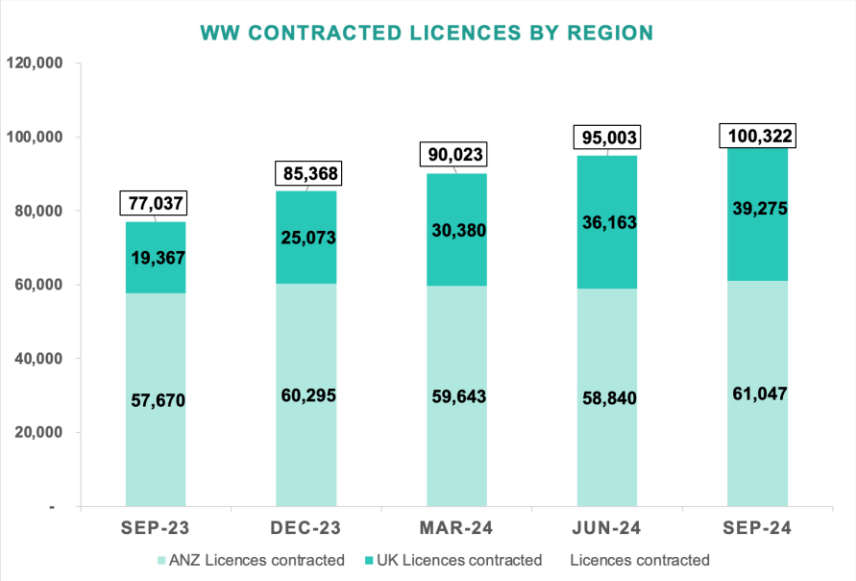
The market penetration within aged care of the PainChek Adult App is circa 30% in Australia and 8% in the UK. Renewal rates of customers continue to be at around 90% in Australia and 78% in the UK.

The pipeline for growth continues to be well supported by resellers and partners, in addition to the continued marketing activities of the company and presentations at large industry conferences such as the UK Care Show, International Dementia Conference. Large customers with over 1,000 beds continue to comprise more than half of the 100,000 contracted licences. These larger, multi-facility clients who have size and capability, are more advanced in the digital transformation process.

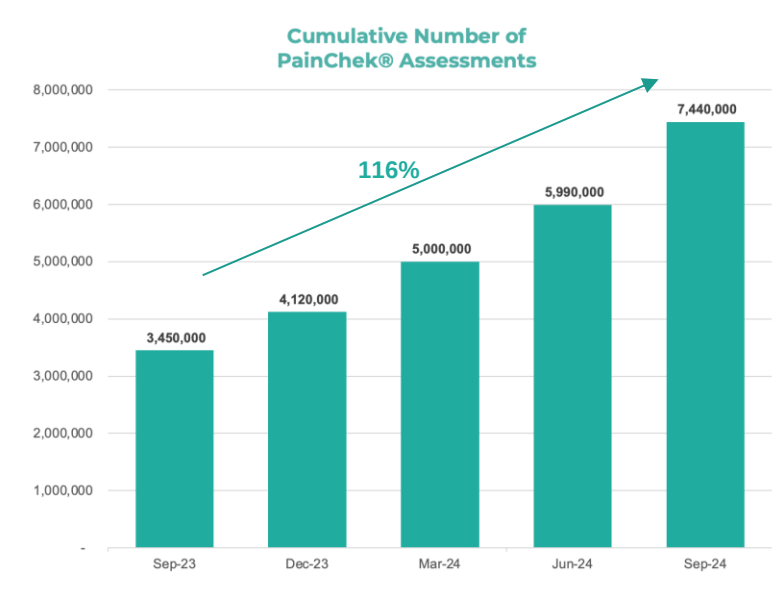
61,705 licences have been implemented, a net increase of 6% over the prior quarter and 11% increase over the prior year. In the UK net implementations were more than 5,000 licences in the past quarter. The 6% increase in implemented licences follows the timing of new sales implementations and some attrition at the start of the quarter.

The backlog of licenses to implement is often a result of large customers requiring staged rollouts across their locations, but are better resourced to ensure successful implementation. PainChek has continued to recruit new staff and partners in the UK to increase the implementation of these customer contracts.





The global PainChek utilitisation continues to grow, with over 7.4 million cumulative PainChek clinical assessments conducted as of 30 September 2024, an increase of 116% over the previous year and 24% over the prior quarter, reflecting continued strong growth in clinical use and implementation progress. Utility is a key driver of ongoing client retention.



ANZ market

In ANZ PainChek has maintained a growing market penetration; there are over 61,000 contracted licences, a 4% growth for the quarter and 6% growth over the prior year, across ~750 aged care facilities representing approximately 30% of the Australian market.

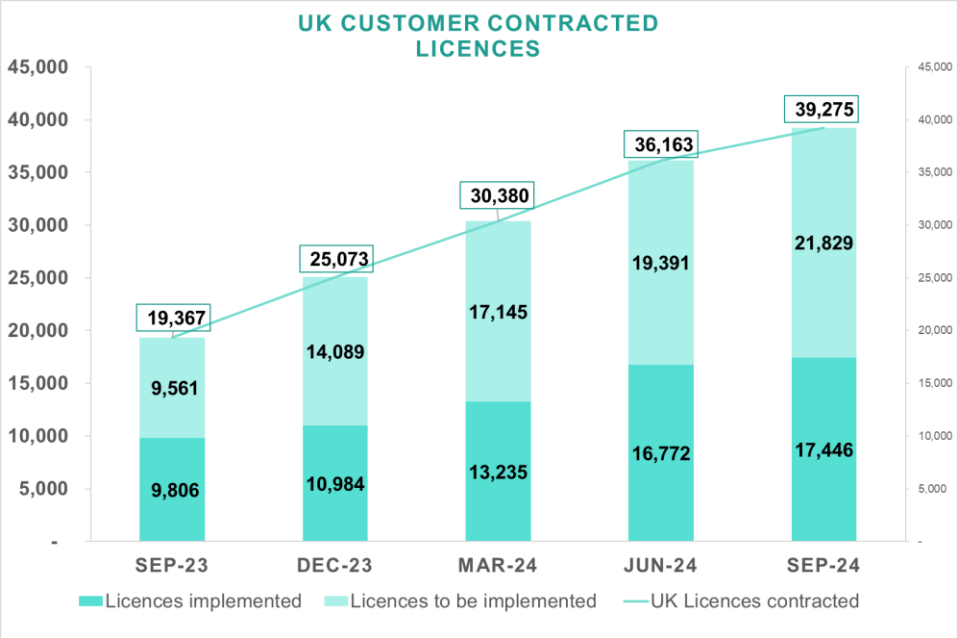
PainChek secured ~4,000 new licenses including larger providers Southern Cross Care SA,NT,VIC (~1,400 licenses), Montefiore Homes (~630 licenses) and Bene Home Care (~650 licences). In addition to this, PainChek has kicked off a pilot with Princess Alexandra Hospital, Dementia and Delirium Nursing Service.

Contracts with new clients are activation based, whereby a scheduled rollout and payment plan is agreed upon at the contract signing stage. This has started to have a positive impact on cashflow and client implementation.

Implemented licenses have remained steady as small to medium sized implementations have offset attrition. There is a pipeline of larger clients with a longer implementation cycle that once completed, will result in a significant positive impact on the number of licenses implemented. With PainChek's mix of larger clients, it now has 44,259 implemented vs 45,748 in September 2023 and 43,327 in June 2024. This reflects the shift in mix to new larger clients. Of the 16,788 to be implemented, 4,848 is across two clients with 36 months contract, who have a staged rollout to fit in with their digital transformation programmes.

UK market

PainChek's market penetration in the UK continues to grow significantly, validating the Company's ability to grow rapidly in overseas markets and as it prepares for US market entry post FDA clearance. There are over 39,000 contracted licences across more than 1,000 aged care facilities, a 103% year on year increase and 9% in the quarter. The ARR of these licences, when fully implemented, is $2.1M in a circa $25M UK residential aged care market, reflecting 8% penetration in a market opportunity of 500,000 beds.



Some of PainChek's larger UK clients include:

- Oakland Care – 1,000 beds across 10 homes following a successful pilot in one of its services, where over 20,000 pain assessments were conducted over 6 months. A significant reduction in pain was identified during this time period, and several case studies captured showed how PainChek data influenced care and treatment plans.
- Berkley Care – 800 beds over 12 luxury care homes.

Progress continues with tapping into Government funding in the UK; The University of Hertfordshire and Health Innovation East is independently evaluating the benefits of using PainChek across Care Homes in Bedford Luton and Milton Keynes ICB, as part of the government-sponsored Adult Social Care Technology Fund (ASCTF). The first interim report from care homes using PainChek in Central Bedfordshire Council has shown some promising results, with a significant reduction in the quantity and cost of pain medication being prescribed to residents living in Care Homes following the implementation of PainChek. Further reports are to be written throughout the 15 month project, where falls, hospital admissions, workforce capacity and dependency will also be explored. If PainChek proves successful during the project across BLMK ICB, the DHSC could support a national rollout of PainChek across England.

South West London ICB has funded 820 licenses across 20 Care Homes. The technology was well received following the interim report, with several case studies showing how Care Homes have engaged with Allied Healthcare professionals to support decision-making, which has led to the discontinuation of unnecessary long-term pain medications.

Training approaches have been streamlined to deliver implementation at a faster pace to PainChek's larger clients, with rollouts at Coverage Care Services (624 beds), Abbey Healthcare (666 beds) and TLC Care (429 beds).

North America market

US FDA (Food and Drug Administration) regulatory clearance

PainChek's US market entry strategy remains on track after positive results from its Adult App US clinical validation study and statistical analysis, which demonstrated high performance in a paired study with the Abbey Pain Scale.

The PainChek validation study recruited a total of 105 patients living in Nursing Homes in five sites in Iowa and New York who were assessed for pain in a comparative study with the Abbey Pain Scale. The validation study has shown comparative performance with Abbey Pain Scale with regards pain intensity agreement and test-retest reliability.

PainChek is now in the process of submitting the results of the validation data along with the other required documentation to FDA for De Novo regulatory clearance. This submission is expected in November 2024.

PainChek will also be submitting the validation data for peer-reviewed journal publication and for future US medical conferences in 2025 as part of the US market entry strategy. PainChek can confirm that the validation study results are consistent with other previous studies of evaluating the psychometric properties of observation pain assessment tools.

Whilst FDA state that DeNovo application decisions typically require 150 days, the fact that PainChek has worked closely with the FDA with two previous pre-sub supplements to clarify the desired end points holds the Company in good stead for a timely response from FDA.

In the meantime, PainChek continues to grow new clients in Canada and build new integration, sales and marketing partnerships with North American aged care and hospital providers.

North America partners

The North American market is the largest healthcare market in the world with 2,000,000 long term care beds and the PainChek Adult App market opportunity is estimated to be worth $100M USD per annum.

PainChek has already successfully integrated with PointClickCare (PCC) and that integration is being used across five Canadian aged care facilities while other pre-marketing activity with PCC has commenced.

PCC is the leading cloud-based healthcare software provider for North America's long-term and post-acute care (LTPAC) and senior care industries. It has 50% of the 2,000,000 US and Canadian long term beds under licence.

PainChek is progressing with negotiations to contract with new integration and reseller partners in North America to enable a rapid market entry once FDA clearance is achieved.

Children's and Infant App staged rollout

PainChek's work towards the commercialisation of PainChek® Infant has continued to progress, with a focus on the large, global consumer market. The Infant market opportunity extends to up to 400 million pre-verbal children, of which 150 million are born to first time parents every year.

PainChek® Infant app is a fully inclusive App and provides a range of other value adding features for parents and family members, including:

- 3-second pain assessment analysis

- Monitoring historical pain events
- Documenting treatments, including medications
- Self-guided in-app training
- User-friendliness in a non-clinical environment

Entering the final phase of testing prior to a broad market entry in Australia in 2025, followed by global markets, PainChek has successfully launched the PainChek® Infant Early Access Program (EAP), which invites a small group of early adopters to use the app and provide valuable feedback. The program's primary objectives are to validate the product-market fit and target audience, as well as establishing industry partnership and distribution channels.

During the quarter, PainChek has engaged with industry experts Mamamia and Kiindred to organically attract first time parents in Australia with infants aged between 1 month to 12 months and has successfully recruited its first 50 members creating awareness amongst parents and medical professionals.

With a cumulative target of up to 200 members by Q4 CY24, recruitment is now projected to increase as members can now download PainChek infant directly from the App store. This not only optimises the member experience, but also opens acquisition through new distribution channels like pharmacies and medical practices. New recruitment activities include expert webinars, new partner explorations and channel testing.

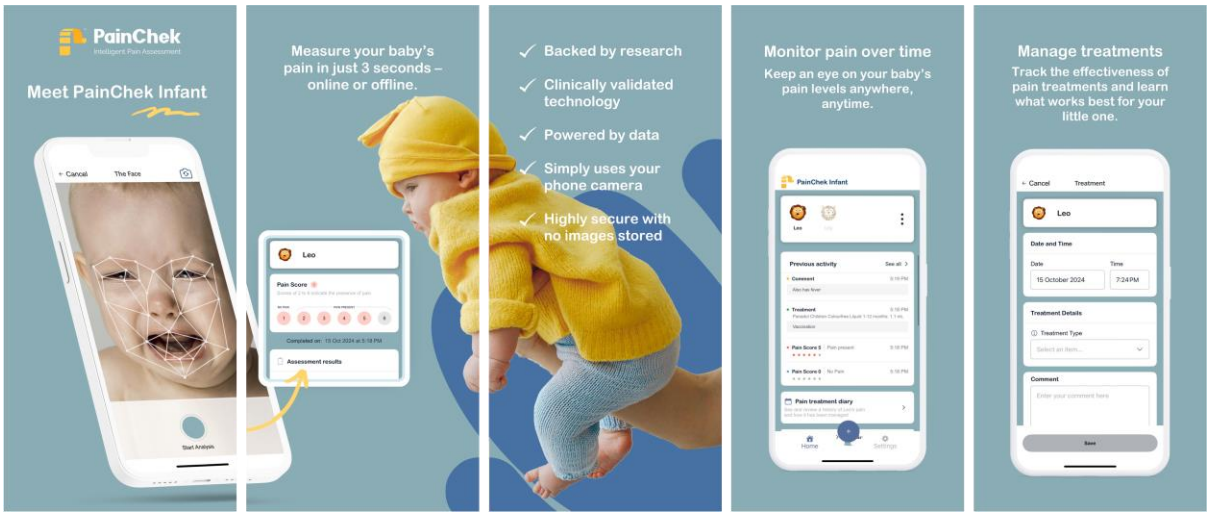


Figure 1 App store listing

Other business updates

Global integration partners

PainChek maintains a close partnership with Care Management System (CMS) and Electronic Medication Administration Record (eMAR) providers. This strengthens the value proposition of PainChek and increases scalability to penetrate markets through the reselling or referrals from those partners looking for additional revenue streams and differentiation of product.

Clinical Research

As previously reported, two Hollywood Private Hospital (WA) based research projects are underway:

- The manuscript covering the effectiveness of the PainChek training has now been revised and resubmitted to the Journal of Medical and Internet Research. This is a study into improving pain assessment for hospitalised older adults following orthopaedic surgery using a technology-driven pain assessment.
- A project has been established and ethical approval obtained for an effectiveness-implementation pilot study to improve pain assessment for hospitalised older adults with cognitive impairment using a technology-driven pain assessment tool. This will commence in January 2025.

Additional clinical studies being progressed include:

- Funding has been awarded by The School of Nursing and Midwifery, Edith Cowan University to support the completion of Phase 1 of the study into the feasibility of using PainChek in the hospital emergency department (ED). The study is conducted at Sir Charles Gairdner and Fiona Stanley Hospitals in Western Australia. In addition to governance and ethics, training and evaluation, it can contribute to the analysis of the audit of pain assessment practice for patients with cognitive impairment in ED. Phase 2 of the implementation will commence in 2025 with additional grant funding being sought.
- Grant funding has been obtained for the implementation study of PainChek within a Geriatric/Rehabilitation Ward at Singapore General Hospital, Singapore. Application for ethics approval is now underway.
- Videos have been processed and are ready for assessment in the evaluation of the validity of PainChek Infant for the assessment of pain in neonates undergoing frenectomy. Ethics approval for the project has been received.

PainChek is currently working with a research team at the University of Applied Sciences and Arts (HSBI) Bielefeld, Germany.

- The collaborative work includes the validation of the German version of the PainChek instrument in an aged care setting. PainChek will be validated against the German version of the Pain in Advanced Dementia scale (**PAINAD-G)** also know as Beurteilung von Schmerz bei Demenz (**BESD**), which is a widely used pain assessment tool used in people living with advanced dementia in Germany. We envisage conclusion of data collection phase of the study in April 2025.

PainChek continues with the “Pain Profiling” research and the decoding manuscript in final process of internal review prior to submission following a study of some 2.2 million pain assessments. This initiative will expand current PainChek indications for use and has revealed that clear relationships exist between pain intensity and the frequency of occurrence of facial and on-facial pain indicators.

Presentations

- Prof Jeff Hughes delivered a presentation entitled: 'PainChek – Giving a voice to those who cannot tell you they're in pain' as an invited speaker at the 9th World Rett Syndrome Congress, Gold Coast, Queensland, October 2024
- A/Prof Rosemary Saunders presented a poster entitled: 'Assessing pain using an automated facial recognition and analysis app to improve pain assessment in hospitalized older patients' at the Australian College of Nursing National Forum, Cairns, Queensland, in August 2024
- Prof Jeff Hughes presented two posters at the Hammondcare International Dementia Conference in Sydney, New South Wales, in September 2024. The posters are entitled: (i) 'Pain in people living with dementia: A significant contributor to caregiver burden' and (ii) 'Assessing pain using a technology-enabled app (PainChek Universal) to improve pain assessment for hospitalised older adults'

Recent PainChek Related Publications

- Atee M, Whiteman I, Lloyd R, Morris T. Behaviours and psychological symptoms of childhood dementia: two cases of psychosocial interventions. Palliative Care and Social Practice. 2024 Sep;18:26323524241273492.
- Cascella M, Leoni ML, Shariff MN, Varrassi G. Artificial Intelligence-Driven Diagnostic Processes and Comprehensive Multimodal Models in Pain Medicine. Journal of Personalized Medicine. 2024 Sep 16;14(9):983.
- Tagliafico L, Maizza G, Ottaviani S, Muzyka M, Rovere FD, Nencioni A, Monacelli F. Pain in non-communicative older adults beyond dementia: a narrative review. Frontiers in Medicine. 2024 Aug 15;11:1393367.
- Chejor P, Atee M, Cain P, Whiting D, Morris T, Porock D. Pain prevalence, intensity, and association with neuropsychiatric symptoms of dementia in immigrant and non-immigrant aged care residents in Australia. Scientific Reports. 2024 Jul 23;14(1):16948.

Financial Update

- The recognised revenue from customers was $760,000 (unaudited) for the quarter and year to date, a 7% increase over the June 2024 quarter and a 17% increase over the September 2023 quarter.
- The completion of significant projects, such as US clinical trials, product improvements, cyber security implementation and technology upgrades have placed the company in a position to get to an operating break even when the implemented ARR increases to approximately $5m. This is before the costs of additional research, product development, corporate operating costs and investments into new markets.

Cashflow

- Cash reserves are $1.7m at the end of September 2024. The FY24 R&D incentive refund is being finalised for lodgement with the ATO, and if required, financing of up to 80%, or approximately $950,000 can be made available against that refund. If the company draws on that financing, then operations can continue for up to two quarters with a continuation of current run rates and completion of payments for US FDA submission (see below). The company is currently finalising arrangements to make that financing available, and is exploring further financing options. The company has successfully raised funds from investors and current shareholders in the past, and expects this support to continue going forward.
- Receipts from customers in the quarter were $915,000 (Q4 FY24: $720,000). Customers paying in advance for the PainChek subscription have an uneven distribution of renewal dates throughout the year, which accounts for some seasonality in receipts, which will not be in line with the revenue reported.

- Research and development payments were $1,057,000 (Q4 FY24: $833,000), the increase is due to final payments for the FDA clinical trials and report. During the period one off costs of $552,000 was paid to suppliers for the FDA related work. The company has invested over $2.0M in the US FDA clinical trials and data collection over the last two years. Those costs will not be repeated assuming the US FDA De Novo regulatory submission is successful as future PainChek FDA new product submissions would use the De Novo clearance as a predicate and therefore be processed through the lower cost and faster track 510K clearance process.
- Advertising and Marketing payments were $195,000 (Q4 FY24: $303,000), the decrease follows high payments in Q4 FY24 for infant app market research and adult app lead generation.
- Staff Costs payments were $1,105,000 (Q4 FY24: $1,325,000), the decrease follows higher payments in Q4 FY24 for new starters, recruitment and payment of superannuation guarantee payments before the year end.
- Administration and Corporate costs payment increased to $418,000 (Q4 FY24: $382,000),
- In accordance with ASX Listing Rule 4.7C.3, the amount of $112,500 stated in section 6.1 of the Appendix 4C paid to related parties and their associates related to director fees and salaries for the quarter. The company made payments to directors during the period of $112,500: $50,000 to non-executive and $62,500 to executive directors.

This announcement has been approved for release by the Board.

For more information:

Natalie Climo
Company Secretary, PainChek
natalie.climo@boardroomlimited.com.au
02 8016 2875

Philip Daffas
CEO, PainChek
philip.daffas@painchek.com
0406 537 235

About PainChek

PainChek® is the world's first regulatory-cleared medical device for the assessment of pain, enabling best-practice pain management for people living with pain in any environment, from those who cannot reliably self-report their pain, those who can, and for those whose ability to self-report their pain fluctuates.

The PainChek® app is available on smartphones and tablets and combines PainChek's AI pain assessment tool, which intelligently automates the multidimensional pain assessment process, with the Numerical Rating Scale (NRS). This hybrid functionality allows accurate, consistent pain assessment at the point of care, and for care to be considered in PainChek's detailed reporting suite, PainChek® Analytics.

Globally, PainChek® has attained regulatory clearance as a medical device in Australia, Canada, the European Union, New Zealand, Singapore, Malaysia, and the United Kingdom, with FDA review in the United States currently in progress.

PainChek® has contracts with over 1,600 aged care facilities, with more than 7,000,000 digital pain assessments conducted to date, and is trusted by thousands of nurses, carers, and clinicians.

Using PainChek®, facilities can:

- Ensure greater consistency, continuity, and diagnostic certainty in pain assessment and management by decreasing subjectivity and removing unintentional assessor bias

- Streamline the pain assessment process for time-poor carers, with access to the PainChek® tool, the NRS, pain trends, and charting in one solution
- Simplify record-keeping and documentation to demonstrate compliance and support funding claims, with all historical pain assessment data in one place
- Enhance engagement with GPs and allied healthcare professionals

Clinical studies conducted in Australian and UK residential aged care centres have been published in various peer-reviewed journals including the Journal of Alzheimer's Disease. An article in BMC Geriatrics indicates that PainChek® is a valid and reliable instrument to assess the presence and severity of pain in people with moderate-to-severe dementia living in aged care. Further information on clinical studies can be found here.

PainChek® has successfully supported accurate pain assessment and management for thousands of adults worldwide living with dementia, disability, or other conditions impacting their ability to self-report pain. Building on the success of this technology, the clinically validated PainChek® Infant app identifies and detects six facial action units indicative of pain in infants aged one month to 12 months.

The need for PainChek as a best-practice pain management solution also extends to older people living at home and with access to home care packages that enable long-term home living. PainChek is expanding into home care by partnering with home care and disability service providers.

For more information, visit: https://painchek.com

+Rule 4.7B

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

PAINCHEK LTD

ABN	**Quarter ended ("current quarter")**
21146035127	**30/09/2024**

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.0	**Cash flows from operating activities**		
1.1	Receipts from customers	915	915
1.2	Payments for		
	(a) research and development	(1,057)	(1,057)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing	(195)	(195)
	(d) leased assets		
	(e) staff costs	(1,105)	(1,105)
	(f) administration and corporate costs	(418)	(418)
1.3	Dividends received (see note 3)		
1.4	Interest received	0	0
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives	0	0
1.8	Other (GST)	24	24
1.9	**Net cash from / (used in) operating activities**	**(1,836)**	**(1,836)**

2.0	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(3)	(3)
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		
2.2	Proceeds from disposal of:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	0	0
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		
2.3	Cash flows from loans to other entities		
2.4	Dividends received (see note 3)		
2.5	Other (provide details if material)		
2.6	**Net cash from / (used in) investing activities**	**(3)**	**(3)**

3.0	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	0	0
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options	0	0
3.4	Transaction costs related to issues of equity securities or convertible debt securities		
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings		
3.7	Transaction costs related to loans and borrowings		
3.8	Dividends paid		
3.9	Other (provide details if material)		
3.10	**Net cash from / (used in) financing activities**	**0**	**0**

4.0	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,562	2,512
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,836)	(1,836)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(3)	(3)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	0	0
4.5	Effect of movement in exchange rates on cash held	1	1
4.6	**Cash and cash equivalents at end of period**	**1,723**	**674**

	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	**Current quarter** **$A'000**	**Previous quarter** **$A'000**
5.1	Bank balances	1,723	4,429
5.2	Call deposits	0	0
5.3	Bank overdrafts		
5.4	Other (provide details)		
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**1,723**	**4,429**

		Current quarter $A'000
6.0	**Payments to related entities of the entity and their associates**	
6.1	Aggregate amount of payments to related parties and their associates included in item 1	113
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

	Financing facilities *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the position*	**Total facility amount at quarter end**	**Amount drawn at quarter end**
7.0		**$A'000**	**$A'000**
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	**Total financing facilities**		

7.5	**Unused financing facilities available at quarter end**	
7.6	Include in the below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.	

8.0	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,836)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,723
8.3	Unused finance facilities available at quarter end (item 7.5)	0
8.4	Total available funding (Item 8.2 + Item 8.3)	1,723
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	0.9

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: No, the end of the US FDA clinical trials and technology upgrades will result in reduced cash outflows. In the September quarter, $552,000 was paid for FDA de Novo clearance trial and data analysis, that work is now complete (refer to quarterly update for more detail). Customer receipts have continued to increase with new sales and implementation of contracted licences. Therefore the quarterly net operating cash used will decrease.

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: The company is currently exploring a variety of fundraising options in the December 2024 quarter, including:
-A refund of up to $1.2M is being claimed for FY2024 R&D incentive refund and the company is sourcing financing against that refund, if needed.
-Raising additional capital; The company has successfully raised funds from investors and current shareholders in the past, and expects this support to continue going forward.

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: Yes. The run rate of expenditure will significantly decrease now that the company is ready for US FDA De Novo regulatory submission - over $0.5M was paid in this September 2024 quarter. The company also expects to secure financing against a R&D incentive claim, 80% of a total claim of $1.2M can be financed if needed.

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 30/10/2024

Authorised by: By the board

(Name of body or officer authorising release - see note 4)

Notes

1 This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2 If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, AASB 107: Statement of Cash Flows apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3 Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4 If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5 If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.