

EMVision Medical Devices Ltd

Portability and affordability for brain scans

EMVision Medical Devices Ltd (ASX:EMV) is developing a portable brain scanner for rapid, point-of-care stroke diagnosis and monitoring. The technology uses electromagnetic microwave imaging, the technology developed over 10-years by researchers at the University of Queensland, and potentially offers portability and affordability advantages over the current standard of care cost (MRI/CT scans). EMV listed on the ASX in November 2018, raising \$6m at an issue price of \$0.25/share. It raised a further \$4.5m at \$0.85/share in November 2019 and \$9m at \$1.42/share in July 2020. EMV has conducted a single study with 30 stroke patients receiving both the EMV scan and either an MRI and/or CT scan. The EMV scan was able to identify the type of stroke with an accuracy of 93.3%-96.0% and localise the correct quadrant with an overall accuracy of 86.7%-96.0%. The FDA has recommended the De Novo pathway for the product, designed for low-medium risk, first-of-a-kind products. EMV will engage with the FDA to confirm the required evidence the clinical trial performance data required, assuming and incorporating a pivotal clinical trial with the end design being finalised. The group ended December 2020 with net cash of \$13.0m and in March 2020, in collaboration with the Australian Stroke Alliance, was the recipient of a Medical Research Future Fund Frontiers grant which delivers \$8m in non-dilutive cash funding towards EMVision's product development and clinical validation for hospital and pre-hospital models.

Business model

EMV is pre-revenue and as a result the business model is focused on the continued product development, clinical validation, and regulatory approval processes to bring their first-generation scanning product to market. From a product development perspective work is being done to make the unit smaller, easier to use and robust for large scale manufacturing. Algorithms continue to be refined from earlier learnings. From a regulatory viewpoint EMV continues to engage with the FDA to confirm the required evidence required from clinical trials and an application for the FDA's breakthrough device designation program as they go down the De Novo pathway to approval.

Recent hires ready the company for commercialisation

The company ended December 2020 with \$13m net cash to fund near-term product development and regulatory approvals. EMVision has subsequently had this cash position bolstered having secured an \$8m grant through its successful Stage 2 Medical Research Future Fund bid in collaboration with the Australian Stroke Alliance. EMV has readied its team for its commercialisation stage. The company's in-house commercial product development team has been strengthened with several experienced appointments across software, mechanical, radiofrequency, production and process engineering. Many of these hires include a number of seasoned medtech innovators formerly from Nanosonics (ASX:NAN) and ResMed (ASX:RMD).

A number of ASX medical device peers

The ASX has a number of commercial stage medical imaging companies comparable to EMV including 4D Medical (ASX:4DX) which is focused on commercialising its patented lung imaging platform, XV Technology; Cyclopharm (ASX:CYC) which specialises in diagnostic imaging for lungs utilising nuclear medicine, Micro-X (ASX:MX1) which is engaged in the design, development and assembly of ultra-lightweight carbon nano tube-based x-ray products for the global healthcare and security markets, and Imricor (ASX:IMR) which specialises in developing innovative MRI-compatible medical devices.

Medical Devices

12th March 2021

Share details

ASX Code	EMV
Share price	\$2.70
Market Capitalisation	\$190.9M
Shares on issue	70.7M
Net cash at 31/12/2020	\$13.0M
Free float	67.25%

Share performance (12 months)



Upside Case

- First generation commercial product fabricated
- Successful expanded clinical trials
- Commercial partnerships (e.g. distribution)

Downside Case

- Fails to achieve clinical trial primary endpoint
- Delays in the time to market
- Key personnel risk

Catalysts/upcoming events

- Next gen product development (1HCY21)
- Expanded Clinical trial preparation (1HCY21)
- Commercial & Collaboration Updates (1HCY21)

Comparable companies (Aust/NZ)

4d Medical (ASX:4DX) Micro-X (ASX:MX1),
Imricor (ASX:IMR), Cyclopharm (ASX:CYC)

Top 5 shareholders

Scott Kirkland	5.3%
Ryan Laws	4.6%
John Keep	2.4%
Truebell Capital	2.3%
Dr Ron Weinberger	1.4%

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FINANCIAL SERVICES GUIDE

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