Singular Health Group Ltd: SHG

ASX Announcement

18 August 2022

Singular Health announces FDA 510(k) submission for 3Dicom MD™ DICOM Viewer

- Singular Health has submitted a 510(k) premarket notification to the United States' Food & Drug Administration (FDA) for the 3Dicom MD™ collaborative DICOM viewer software.
- 3Dicom MD™ is a collaborative diagnostic viewer for use by medical practitioners and radiologists to view Digital Imaging and Communication in Medicine (DICOM) scans.
- Real-time collaboration features to allow for multi-disciplinary team meetings and radiologist-practitioner consultations for improved telehealth capabilities.

18 August 2022 – Medical technology company Singular Health Group Ltd (ASX: SHG) ("Singular Health", or "the Company") is pleased to advise that it has submitted a 510(k) premarket notification to the US Food and Drug Administration (FDA) for 3Dicom MD™.

3Dicom MD™ is a standalone Software-as-a-Medical-Device (SaMD) developed by Singular for use by medical practitioners of all specialities, including radiologists and dentists, for the diagnostic viewing of CT, MRI, and PET scans in standard 2D multi-planar views as well as immersive, interactive 3D visualisation using Singular Health's proprietary Volumetric Rendering Platform.

Developed for a post-COVID clinical environment, 3Dicom MD™ features telehealth functionality with in-built remote control, VoIP calling, and text chat for remote collaboration.

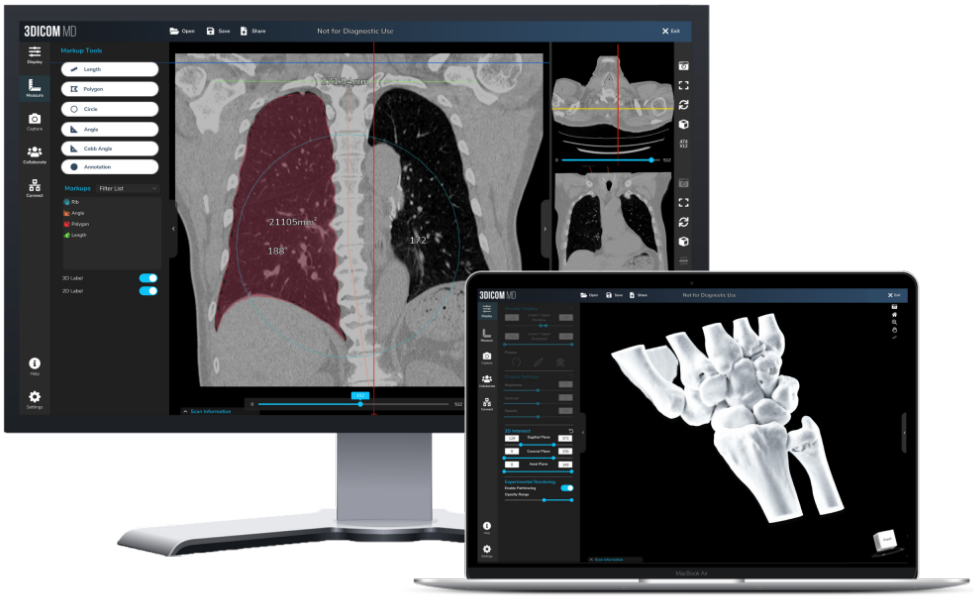

Figure 1: 3Dicom MD™ software operates across both Windows and Mac operating systems with 2D & 3D visualisation

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Since March 2020, Singular Health has adapted both its operations and product development in response to the COVID-19 pandemic, rapid developments in consumer device and standalone VR hardware graphical processing power, and the increase in patient-specific surgical planning and solutions.

Designing, developing, and validating a Software-as-a-Medical-Device (SaMD) product that combines 'traditional' radiological software, with standard 2D visualisation and screen sharing, with interactive 3D visualisation and common collaboration features such as VoIP calling, text chat and even remote control by other medical practitioners has been a worthy challenge for the team at Singular Health, and one that has been justified by the many positive usability tests conducted with medical practitioners both domestically and abroad.

The FDA510(k) review process entails an initial 90-day review period, however this can be extended should the FDA have additional questions or discussions arising from the dossier.

A successful result from the FDA will result in Singular Health having to appoint a US-based agent prior to marketing and selling the diagnostic 3Dicom MD™ software within the United States. The Company is currently in discussions with a number of US-based companies regarding appointment as a US Agent and/or distributor(s) of the software and is currently assessing the optimal capital strategy to maximise the leverage and opportunities that may arise from a successful FDA application, whilst maintaining prudent cost controls.

Singular Health's Chairman, Howard Digby, commented on the milestone, saying:

> "Today's announcement of the 510(k) submission to the US FDA is the culmination of many months of diligent work by the whole team at Singular Health and the regulatory and technical consultants engaged to assist with the extensive testing, validation, and documentation process.
>
> A successful review by the FDA will see Singular Health gain access to the vast US Medical Imaging Software market, valued at USD $885.3 million in 2020[1], with the ability to market the MD tier of the 3Dicom software for diagnostic usage.
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> Development on Singular Health's 3Dicom Surgical software for segmentation, medical 3D printing, and implant planning has been occurring concurrent with the 3Dicom MD™ software development and is well progressed for its own anticipated 510(k) submission.
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> We would like to thank all our shareholders who have supported the Company as it has progressed towards this milestone."

This announcement is authorised for release by the Board of Directors of the Company.

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[1] https://www.researchandmarkets.com/reports/4805205/medical-image-analysis-software-global-market

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About Singular Health:

Singular Health Group Limited (ASX: SHG) is a medical technology company that empowers practitioners and patients via personalised surgical planning solutions that drive better health outcomes.

Singular Health has developed a proprietary Volumetric Rendering Platform (VRP) that leverages existing 2D radiological images to generate fully immersive patient-specific 3D/VR models. Although Singular Health's VRP technology is applicable to other sectors in which the visualisation of dynamic data is crucial, with it already being utilised in the mining sector, the Company's core focus is on the medical sector.
Complementing its VRP technology, Singular Health has acquired Virtual Surgical Planning software and a 25% stake in medical-grade 3D printing company Additive Engineering. These investments represent key milestones in Singular Health's efforts to commercialise its 'Scan to Surgery' initiative, a world-first vertically integrated platform that revolutionises the planning and execution of personalised surgical procedures.

A successful full-scale commercialisation of this end-to-end personalised surgical planning platform will give Singular Health the capability to penetrate a multi-billion-dollar global market opportunity in the medical visualisation and additive manufacturing spaces.

With Singular Health, practitioners are empowered by having the ability to collaborate with producers of patient-specific medical components in real-time while patients benefit from having access to easily comprehensible and enhanced medical information.

To learn more, please visit: www.singular.health