RaaS Watchlist

Singular Health Group Limited

FDA Clearance For Key Cloud Product

Healthcare

21 January 2026

Singular Health Group Limited (ASX:SHG) is an Australian medtech company focused on improving medical data interoperability. Its flagship software, 3DICOM™, enables the seamless sharing of medical images across incompatible systems – reducing inefficiencies and unnecessary costs. In 2025, SHG secured its first major US commercial deal with Provider Network Solutions (PNS), a Managed Service Organisation (MSO) that works with health plans (health insurers), primary care providers and specialists. On 13 January 2026, SHG announced FDA 510(k) clearance for the cloud version of its flagship product, 3DICOM MD® Cloud, improving the prospects for the company to further commercialise its product suite. This is a key development as detailed in this report and we expect several catalysts in 2026 for the company that may drive the share price higher.

Business Model

SHG creates value for its MSO and health plan clients by reducing the number of unnecessary duplicate scans that are taken in the process of diagnosing and caring for patients. Currently in the US healthcare system, poor imaging interoperability means that new imaging exams are often undertaken after a patient leaves the hospital network for follow-up treatment with Primary Care Physicians (PCPs), specialists and clinicians. This typically results in delayed diagnosis, delayed care and unnecessary costs. 3DICOM™ enables the transfer of medical imaging records between healthcare systems, addressing the above issue.

FDA 510(k) Clearance For 3DICOM MD® Cloud Product

On 13 January 2026, the company announced that its 3DICOM MD® Cloud product had successfully received FDA 510(k) clearance, following an initial submission on 28 November 2025. This regulatory milestone was concluded in 40 days, versus the typical 90-day review process, indicating the quality and robustness of the submission and reflecting the rigorous testing and validation completed for 3DICOM MD® Cloud. This speed implies that the FDA was satisfied with SHG's validation data regarding:

- Data integrity: the fidelity of images transmitted and rendered via the cloud;
- Latency and performance: the ability of the cloud rendering engine to deliver diagnostic-quality images without clinically significant lag;
- Cybersecurity: the robustness of the platform against data breaches; and
- Diagnostic functionality: the accuracy, reliability and clinical suitability of the diagnostic tools available through the viewer.

This speed of approval is non-trivial and reflects management's strong capability to navigate complex regulatory and compliance processes, including promptly and comprehensively addressing FDA requests for additional information.

Pivot To The Cloud

While SHG had already received FDA clearance for its *desktop* 3DICOM MD® software in October 2022, the clearance of its modern *cloud* product represents a fundamental shift in commercial scalability to an enterprise-grade cloud platform. It also improves the potential for customer adoption as cloud-based deployment removes the need for complex hardware and desktop installations. Legacy software often relies on 'thick client' installations, requiring software to be physically installed on each workstation, which creates significant friction. Instead, cloud-native deployment allows users to access the software via a standard web browser without installing software or requiring specialised hardware. Critically, this approach should further enable the MSO-led strategy described in our Initiation Report on SHG.

Share Details

ASX code	SHG
Share price (20-Jan)	$0.26
Market capitalisation	$82.0M
Shares on issue	309.4M
Options (various strike prices)	104.5M
Cash	$12.2M
Free float	96.4%
Avg daily volume (12 mths)	0.7M

Share Performance (12-months)

Upside Case

- Success in PNS pilot
- Further customer wins
- Improvement in contract terms

Downside Case

- PNS pilot fails
- Failure to win customers beyond PNS
- Funding risk – SHG is currently loss making

Board and Management

Howard Digby	Non-Executive Chairman
Denning Chong	MD & CEO
Andrew Just	Non-Executive Director
Martina Mariano	Chief Operating Officer

Company Contact

Denning Chong (MD and CEO)
+61 403 193 168
denning@singular.health
https://singular.health

RaaS Contact

Naheed Rahman*
+61 422 314 710
naheed.rahman@raasgroup.com

*** Analyst owns shares**

FDA clearance of a cloud product is also a material development for SHG as we believe that many potential SHG customers are keenly awaiting the availability of a cloud product before engaging commercially with SHG.

Increased High-Volume Modalities Captured In This FDA Clearance

The FDA clearance also covers expanded imaging modality support to now include the 'high-volume' modalities of X-ray and ultrasound, in addition to the 'high-value' advanced modalities of CT, MRI and PET that were already covered in the previous FDA clearance of SHG's desktop product. This materially widens clinical applicability and potential use cases, covering nearly all diagnostic imaging procedures performed annually in the US.

The advanced modalities of CT, MRI and PET command high rates (US$300 to US$2,000+), but cover only ~25% of total imaging volumes in the US. Basic modalities of X-ray and ultrasound have lower rates (US$30 to US$150) but constitute the vast majority of medical imaging, representing the remaining ~75% of diagnostic imaging volumes. It's critical that X-rays and ultrasounds are covered as they represent the vast bulk of imaging by volume and are often used by PCPs as first-line diagnostics. From a commercial perspective, it seems that covering all major modalities for diagnostic imaging is a prerequisite for enterprise-wide adoption.

Exhibit 1: Modality usage in the US

Metric	X-ray	Ultrasound	Computed Tomography (CT)	Magnetic Resonance (MRI)	Positron Emission Tomography (PET)
Annual volume	320m[1]	45m[2]	93m[3]	40m[4]	2m[5]
Share of total volume	64%	9%	18.5%	8%	0.5%
SHG status	Newly cleared	Newly cleared	Previously cleared	Previously cleared	Previously cleared

Source: Various, see footnotes

Upcoming Anticipated Events

There are a number of key developments that investors should look out for in the next six months:

- December 2025 quarterly report, to be released in late January 2026. This should provide an insight into the company's cash burn, and its cash at bank which should be enough to fund operations to profitability.
- Life Radiology update in early 2026. A pilot study with Life Radiology diagnostic clinic in Florida commenced in mid-2025, to validate the performance and integration of 3DICOM™ within an operational radiology practice. We anticipate that a successful outcome of the pilot could lead to a small contract, which nonetheless provides further validation of the product.
- Half-year report to be released in February 2026.
- March 2026 quarterly report, to be released in April 2026.
- June 2026 quarterly report, to be released in July 2026. By this time, we expect the first set of results from the PNS pilot (following the rollout of a further 500 3DICOM™ licences in the March 2026 quarter, taking the total to 750 licences rolled out of the total 1,000 for the pilot). This is perhaps the key development for SHG investors in the near term, as any result showing a meaningful decrease in duplicate images and costs would be seen as a 'success', and a clear proof-point that SHG's solution is of value to its customers. We expect that a success scenario would also result in the pilot broadening to PNS's wider network of up to 3,500 physicians, and other potential customers signing on.
- New customer contract announcements.

[1] https://www.360researchreports.com/market-reports/diagnostic-x-ray-imaging-market-201785

[2] https://www.marketgrowthreports.com/market-reports/ultrasound-imaging-market-112204

[3] https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2832778

[4] https://www.globenewswire.com/news-release/2025/11/05/3181604/0/en/Magnetic-Resonance-Imaging-MRI-Market-Size-is-Expected-to-Reach-USD-2-619-Million-by-2034.html

[5] https://www.auntminnie.com/clinical-news/molecular-imaging/article/15625434/imv-pet-scan-volume-continues-growing-at-steady-pace

FINANCIAL SERVICES GUIDE

RaaS Research Group Pty Ltd

ABN 99 614 783 363

Corporate Authorised Representative, number 1248415, of

BR SECURITIES AUSTRALIA PTY LTD; ABN 92 168 734 530; AFSL 456663

Effective Date: 26th March 2024

About Us

BR Securities Australia Pty Ltd (BR) is the holder of Australian Financial Services License ("AFSL") number 456663. RaaS Research Group Pty Ltd (RaaS) is an Authorised Representative (number 1248415) of BR.

This Financial Service Guide (FSG) is designed to assist you in deciding whether to use RaaS's services and includes such things as who we are, our services, how we transact with you, how we are paid, and complaint processes

Contact Details, BR and RaaS

BR Head Office: Level 1, 160 Edward Street, Brisbane, QLD, 4000 www.brsecuritiesaustralia.com.au

RaaS:. c/- Rhodes Docherty & Co Pty Ltd, Suite 1, Level 1, 828 Pacific Highway, Gordon, NSW, 2072.

P: +61 414 354712

E: finola.burke@raasgroup.com

RaaS is the entity providing the authorised AFSL services to you as a retail or wholesale client.

What Financial Services are we authorised to provide? RaaS is authorised to

- provide general advice to retail and wholesale clients in relation to
  - Securities

The distribution of this FSG by RaaS is authorized by BR.

Our general advice service

Please note that any advice given by RaaS is general advice, as the information or advice given will not take into account your particular objectives, financial situation or needs. You should, before acting on the advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Prospectus, Product Disclosure Statement or like instrument. As we only provide general advice we will not be providing a Statement of Advice. We will provide you with recommendations on securities.

How are we paid?

RaaS earns fees for producing research reports about companies we like, and/or producing a financial model as well. When the fee is derived from a company, this is clearly highlighted on the front page of the report and in the disclaimers and disclosures section of the report. Sometimes we write reports using our own initiative.

Associations and Relationships

BR, RaaS, its directors and related parties have no associations or relationships with any product issuers other than when advising retail clients to invest in managed funds when the managers of these funds may also be clients of BR. RaaS's representatives may from time to time deal in or otherwise have a financial interest in financial products recommended to you but any material ownership will be disclosed to you when relevant advice is provided.

Complaints

If you have a complaint about our service, you should contact your representative and tell them about your complaint. The representative will follow BR's internal dispute resolution policy, which includes sending you a copy of the policy when required to. If you aren't satisfied with an outcome, you may contact AFCA, see below.

BR is a member of the Australian Financial Complaints Authority (AFCA). AFCA provide fair and independent financial services complaint resolution that is free to consumers.

Website: www.afca.org.au; Email: info@afca.org.au; Telephone: 1800931678 (free call)

In writing to: Australian Financial Complaints Authority, GPO Box 3, Melbourne, VIC, 3001.

Professional Indemnity Insurance

BR has in place Professional Indemnity Insurance which satisfies the requirements for compensation under s912B of the Corporations Act and that covers our authorized representatives.

DISCLAIMERS and DISCLOSURES

This report has been commissioned by Singular Health Ltd and prepared and issued by RaaS Research Group Pty Ltd, trading as Research as a Service. RaaS Research Group has been paid a fee to prepare this report. RaaS Research Group's principals, employees and associates may hold shares in companies that are covered and, if so, this will be clearly stated on the front page of each report. This research is issued in Australia by RaaS Research Group and any access to it should be read in conjunction with the Financial Services Guide on the preceding two pages. All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable. Opinions contained in this report represent those of the principals of RaaS Research Group at the time of publication. RaaS Research Group provides this financial advice as an honest and reasonable opinion held at a point in time about an investment's risk profile and merit and the information is provided by the RaaS Research Group in good faith. The views of the adviser(s) do not necessarily reflect the views of the AFS Licensee. RaaS Research Group has no obligation to update the opinion unless RaaS Research Group is currently contracted to provide such an updated opinion. RaaS Research Group does not warrant the accuracy of any information it sources from others. All statements as to future matters are not guaranteed to be accurate and any statements as to past performance do not represent future performance.

Assessment of risk can be subjective. Portfolios of equity investments need to be well diversified and the risk appropriate for the investor. Equity investments in listed or unlisted companies yet to achieve a profit or with an equity value less than $50 million should collectively be a small component of a balanced portfolio, with smaller individual investment sizes than otherwise.

The science of climate change is common knowledge and its impacts may damage the global economy. Mitigating climate change may also disrupt the global economy. Investors need to make their own assessments and we disclaim any liability for the impact of either climate change or mitigating strategies on any investment we recommend.

Investors are responsible for their own investment decisions, unless a contract stipulates otherwise. RaaS Research Group does not stand behind the capital value or performance of any investment. Subject to any terms implied by law and which cannot be excluded, RaaS Research Group shall not be liable for any errors, omissions, defects or misrepresentations in the information (including by reasons of negligence, negligent misstatement or otherwise) or for any loss or damage (whether direct or indirect) suffered by persons who use or rely on the information. If any law prohibits the exclusion of such liability, RaaS Research Group limits its liability to the re-supply of the Information, provided that such limitation is permitted by law and is fair and reasonable. Copyright 2026 RaaS Research Group Pty Ltd (A.B.N. 99 614 783 363). All rights reserved.