Singular Health Group Ltd: SHG

ASX Announcement

29th July 2022

ACTIVITIES REPORT FOR THE QUARTER – 30 JUNE 2022

Highlights

- Completion of Stage 1 Audit for ISO13485 and Medical Device Single Audit Program (MDSAP) for FDA, TGA and Health Canada certification. Stage 2 Audit scheduled for Q1 FY23.
- 3Dicom 3.0 released in late May, with the 3Dicom Patient application monetised and launch of a new R&D version with 100+ active, paying subscribers added in June.
- License of initial Artificial Intelligence (AI) model for craniomaxillofacial segmentation and scoping of a consolidated third-party AI marketplace within 3Dicom software.
- Partly owned Australian Additive Engineering (AAE) facility fully operational and promoted titanium and polymer 3D printing at Australian Manufacturing Week.
- Attendance at AANS Conference in Philadelphia generates strong interest from potential US-based clients.

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29 July 2022 – Medical technology company Singular Health Group Limited (ASX: SHG) ("Singular" or the "Company") is pleased to provide its Appendix 4C cash flow statement for the June 2022 Quarter (Q4 FY22) along with the following financial and operational update.

Singular passes Stage 1 of ISO13845 and MDSAP certification

Certification and regulatory approvals are seen as fundamental to the long-term success and intrinsic value of the Company as it strives for full-scale commercialisation. They both present substantial barriers to entry into the highly regulated medical device sector, where Singular will be marketing its unique medical technology platform and associated services. In order to meet this challenge, the June 2022 Quarter saw Singular take a number of significant steps toward expanding on its ISO13845 certification by enrolling in the Medical Device Single Audit Program (MDSAP).

MDSAP opens the way for the Company to consolidate audits for the United States' Food & Drug Administration (FDA), Health Canada and TGA at the same time as ISO13485. Whilst joining MDSAP is a strenuous process, Singular passed the initial audit in late June. The Company is now targeting September 2022 for the completion of the Stage 2 Audit and full certification.

To assist with the MDSAP regulatory documentation and the finalisation of FDA 510k Submission for Singular's 3Dicom MD, Singular has appointed two highly experienced regulatory and technical consultants. 3Dicom MD has passed comparative bench testing and the FDA 510k dossier preparation is well advanced for an anticipated submission in the Company's Q1 FY23.

Commercialisation of 3Dicom Patient & 3Dicom R&D and launch of new 3Dicom website

The Company successfully launched v3.0.0 3Dicom R&D and 3Dicom Patient non-diagnostic versions of the software for universities, students, veterinary clinics, and patients in May 2022. 3Dicom 3.0.0 is the penultimate version of 3Dicom prior to FDA submission.

This latest update comes with multiple enhancements, headed by:

- Many new features requested by initial users that are required for the substantial equivalence determination for FDA 510k for 3Dicom MD
- A new streamlined account management and billing system
- The release and commercialisation of 3Dicom Patient and 3Dicom R&D.

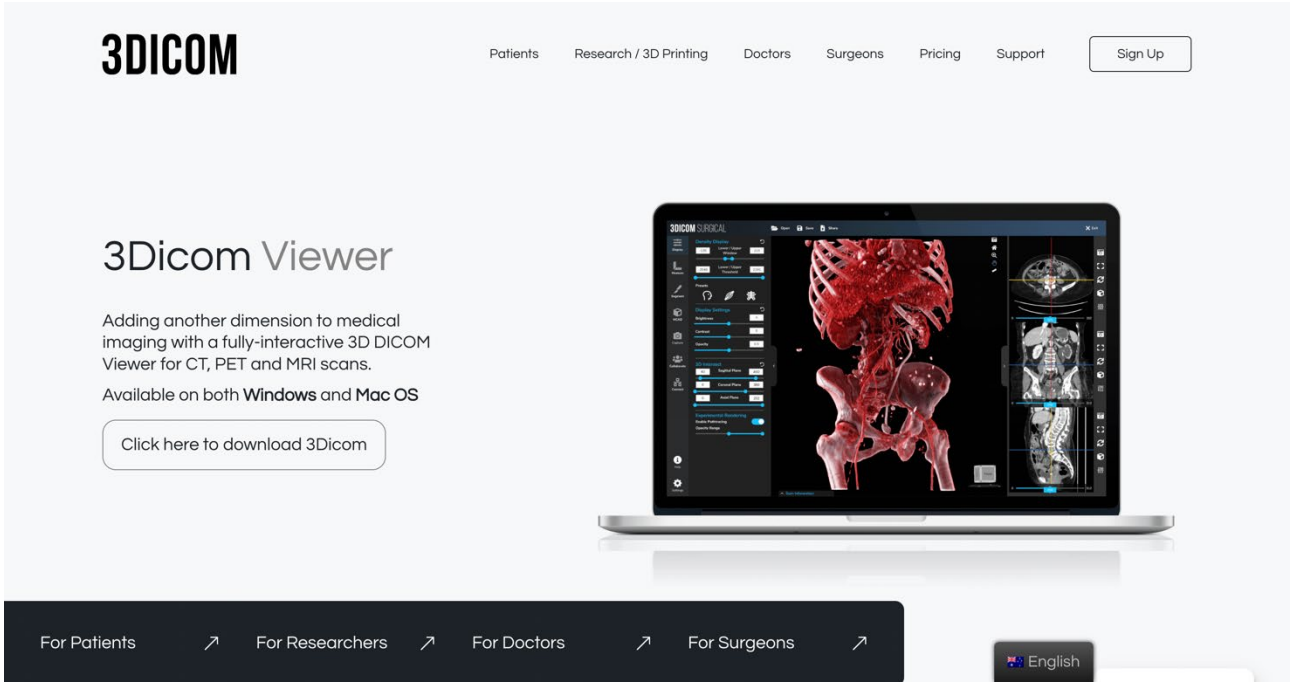

Figure 1: The new 3Dicom Website

Singular also launched a new 3Dicom website, which allows users to fully explore the innovative capabilities of the different versions 3Dicom, namely "Patient", "MD", "Surgical" and "R&D" tiers, which are now available to download on both Mac and Windows.

A Virtual Reality companion application with simple and secure wireless transfer of scans from desktop to VR is anticipated for release on the Oculus Store in the September 2022 Quarter.

Some of the notable features of 3Dicom 3.0.0 include:

- The inclusion of hyper-realistic colour rendering of the 3D models of patient-specific anatomy from standard scans using advanced raytracing.
- The ability to host collaborative calls in 3Dicom MD and Surgical with inbuilt voice and text chat functionality to collaboratively interact with the 3D model in real-time from anywhere.
- The added ability to import medical Computer Aided Design (CAD) files of implants, guides and segmented anatomy/pathologies and superimpose them on the actual anatomy in 3D.
- A newly introduced 2D to 3D annotation tool that allows radiologists and medical practitioners to add annotations in familiar, traditional 2D views and immediately see it in the 3D view too.
- A fast and secure medical file sharing system, developed in-house and known as Medical File Transfer Protocol (MFTP), that enables wireless transfer of scans.

The 3Dicom MD and Surgical tiers are intended for eventual use as diagnostic and/or treatment planning and are therefore classed as Software-as-a-Medical-Devices (SaMDs). Given this, they will require regulatory certification prior to commercialisation.

However, the 3Dicom Patient and 3Dicom R&D tiers are clearly labelled and marketed for non-diagnostic use and have already been purchased in more than 30 countries by patients, academics, and medical device developers as an educational and scientific software.

With the ability to leverage in-built segmentation tools to label medical images in 2D and 3D, create binary masks for AI (artificial intelligence) training datasets, and export 3D printable anatomical models, 3Dicom R&D has been popular with medical AI developers and anatomy educators. Since the launch of the website in June 2022, the Company has acquired over 100 new paying subscribers.

Third Party AI Model Marketplace & Research Agreement with ReLu AI

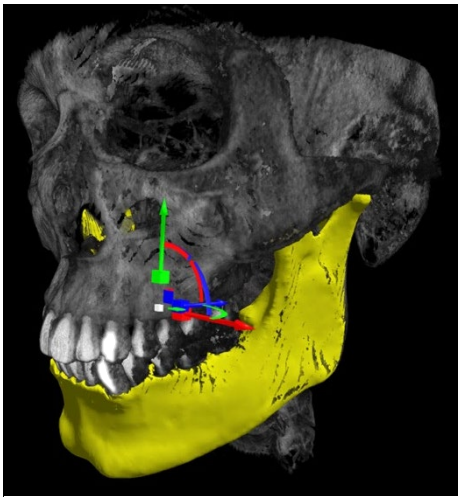

Figure 2. Segmented mandible using the ReLu AI segmentation algorithm

Following the successful Kickstart 1 and 2 AI projects with CSIRO, which focused on semi-automatic segmentation and 3D visualisation of specific anatomy in CT scans in the 3Dicom software, the Company has been evaluating further AI development opportunities both through internal programs or through licensing arrangements.

During the Quarter, Singular signed a research agreement with a Belgium-based start-up, ReLu, to licence their craniomaxillofacial segmentation model for research and evaluation purposes.

The model automatically segments individual teeth, mandible and maxilla from CT scans within minutes. After the end of Q4 FY22, this model was provided to Singular and is now being integrated into 3Dicom R&D.

Following the release of 3Dicom R&D as a promising platform for the creation of medical AI datasets, and ultimately the visualisation and testing of new AI models, Singular advanced a number of discussions during Q4 FY22 with established medical AI companies and data repositories about the creation of a third-party AI marketplace within 3Dicom R&D.

With the 3Dicom software providing a central location for the visualisation of medical images, the ability for AI developers to market their models on a per-use basis right at the point of care, and the ability for practitioners to access multiple AI models all in a single location, provides a compelling value proposition to both sides of the potential marketplace.

Figure 3: Singular Health CEO, Thomas Hanly, and Additive Engineering CEO, Hugh Tevelein, at Australian Manufacturing Week Exposition in Sydney

Additive Engineering Investment Update - Australian Manufacturing Week

Singular Health's Scan to Surgery Initiative continued to evolve in its Q4 FY22. A key component of this Initiative was the Company's investment in Australian Additive Engineering (AAE) in 2021. AAE is a medical grade 3D printing facility in Melbourne with three titanium printers and 2 polymer-based printers for guide and implant manufacture.

Since its full commissioning in the March 2022 Quarter, AAE has been active in promoting their services and acquiring new customers in the medical and industrial space to build on an already expansive customer base. Part of their ongoing marketing initiatives was participation at the Australian Manufacturing Week in Sydney, in June 2022. Singular Health Managing Director, Thomas Hanly, represented the Company at the latter industry event, where he helped showcase the patient specific implants and guides manufactured by Additive Engineering.

Singular COO attends American Association of Neurological Surgeons Annual Conference

In May 2022, Singular Health's Chief Operating Officer (COO), James Hill (second from the left in Figure 4 below) attended the American Association of Neurological Surgeons (AANS) Annual Conference in Philadelphia. As the largest neurosurgical event in the United States, AANS presented a great opportunity to showcase Singular's 3Dicom software on both desktop and virtual reality to a global audience and gain valuable feedback for the cranial implant AI model.

The conference was a success with a large amount of interest shown by surgeons and various medical device manufacturers, who will be able to officially use the 3Dicom MD software once the USFDA certification through the 510K process is granted. The trip to the US was also an opportunity to identify and explore synergies with companies that may contribute to Singular Health's effort in sales and marketing of 3Dicom software both in its current form and as a diagnostic tool post-USFDA certification.

Figure 4: Basiru Sumbundu, Marketing Manager at Kelyniam Global, James Hill, COO at Singular Health, and Ross Bjella, CEO of Kelyniam Global, a patient-specific cranial implant manufacturer

Business Activities Expenditure

In accordance with ASX Listing Rule 4.7C.1, with respect to operating activities expenditure, Singular can confirm total direct operating expenditure was $978,000 for the June 2022 Quarter, consisting of research and development expenses of $297,000, advertising and marketing costs of $94,000, lease payments of $29,000, staff costs of $367,000, administration and corporate costs of $144,000 and ATO payments of $47,000. Net cash used in the operating activities was $974,000 due to cash inflows totalling $1,000 from revenue, and $3,000 from interest received.

Compliance

Pursuant to Listing Rule 4.7C.2, the Company provides the following comparison of its actual group expenditure on the individual items in the "use of funds" statement in its IPO prospectus since the date of its admission to ASX's official list against the estimated expenditure on those items in the "use of funds" statement in the prospectus and an explanation of any material variances.

Use of Funds	Estimate for the two years post ASX admission (as per Prospectus 9 December 2020)	Actual Use to 30 June 2022	% of Total
Costs of the Offer	$505,000	$343,894	68%
Hardware Purchases	$700,000	$261,192	37%
Marketing & IP Certification	$1,163,319	$614,369	53%
Staffing Costs	$1,700,000	$2,155,695	127%
Research and Development	$1,465,000	$932,720*	64%
Working Cap & Corp Costs	$700,000	$1,515,239**	216%
Loan Repayment	$166,681	$166,857	100%
TOTAL	**$6,400,000**	**$5,989,966**	**94%**

* Variations in the actual use of funds will be inclusive of revenues and other material cash inflows including the R&D tax incentive refund of $223,169 as announced in the March 2021 Quarterly

**Variation in Working Cap and Corporate Costs primarily due to inclusion of additional administrative, compliance and corporate costs incurred by the Group and the accounting policy associated with those costs.

Corporate Activities

In accordance with Listing Rule 4.7C.3, the Company advises that payments to related parties of the entity and their associates during the June 2022 quarter amounted to $147,000. Amounts included in 6.1 attached 4C relates to remuneration paid to Directors.

Singular Health Managing Director Thomas Hanly said:

"The June 2022 Quarter saw Singular make further strides towards the end-goal of commercialising its unique medical technology offering. They included the launch in May of v3.0.0 3Dicom R&D and 3Dicom Patient non-diagnostic versions of our software, which represented the end-result of eight months of hard work by our highly skilled in-house technical team.

In addition to our core clinical and diagnostic markets, we are now pursuing recurring revenue opportunities for our software across target market segments of universities, students, veterinary clinics, and patients. 3Dicom 3.0.0 is also significant in that it is the penultimate version of 3Dicom prior to FDA submission.

The launch of our 3Dicom website was also critical to our development process, as it showcases the innovative capabilities of the different versions 3Dicom, including the "Patient", "MD", "Surgical" and "R&D" tiers, to potential clients. The fact that it has already achieved its first 100 active and paying subscribers shows its immense value as a marketing

tool. Going forward, we expect to reduce customer acquisition costs and churn whilst increasing lifetime value of each subscriber.

I was also well pleased with progress made in other areas central to the commercialisation of our technology offering. We are now well on the way to receiving certification and regulatory approvals needed to sell into the highly regulated medical device sector. At the same time, we continued to showcase our 3Dicom suite of software, including the standalone virtual reality application, 3Dicom VSP. Our COO's attendance at the American Association of Neurological Surgeons Annual Conference in Philadelphia during the Quarter generated very positive feedback from both surgeons and potential distributors.

We once again thank our shareholders for their continued support and look forward to releasing further updates on our commercialisation and development journey over the coming months."

Authorised for release by the Board of Directors.

Ends

For further information contact

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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

Appendix 4C

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

Name of entity	
Singular Health Group Limited	
ABN	**Quarter ended ("current quarter")**
58 639 242 765	30 June 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	1	38
1.2	Payments for		
	(a) research and development	(297)	(661)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(94)	(313)
	(d) leased assets	(29)	(84)
	(e) staff costs	(367)	(1,489)
	(f) administration and corporate costs	(144)	(771)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	3	8
1.5	Interest and other costs of finance paid	-	(1)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	387
1.8	Other (Net ATO Payments)	(47)	(94)
1.9	**Net cash from / (used in) operating activities**	**(974)**	**(2,980)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(8)	(11)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(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	2	(5)
2.6	**Net cash from / (used in) investing activities**	**(6)**	**(16)**

3.	**Cash flows from financing activities**	-	-
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
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**	**-**	**-**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	2,120	4,136
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(974)	(2,980)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(6)	(16)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**1,140**	**1,140**

5.	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	1,138	1,120
5.2	Call deposits	-	1,000
5.3	Bank overdrafts	-	-
5.4	Other (Joint Venture Cash Entitlement)	2	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**1,140**	**2,120**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	147
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.

7.	**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 sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $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 box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing 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.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(974)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,140
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	1,140
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.17

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: Yes

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 considering funding options which will allow it to further progress its projects. The Company believes it will be able to raise further equity, or debt, if and as required, as exhibited by the successful completion of its initial public offering of $6 million completed in March 2021 quarter.

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 Company expects to be able to continue its operations and to meet its business objectives based on its response to items 1 and 2 above.

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.

29 July 2022

Date: .....

The Board of Directors

Authorised by: .....
(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.