



# Award of MRFF Frontier Grant & Capital Raising Presentation

4 March 2021

ASX: 4DX

4DMedical Limited | ACN 161 684 831

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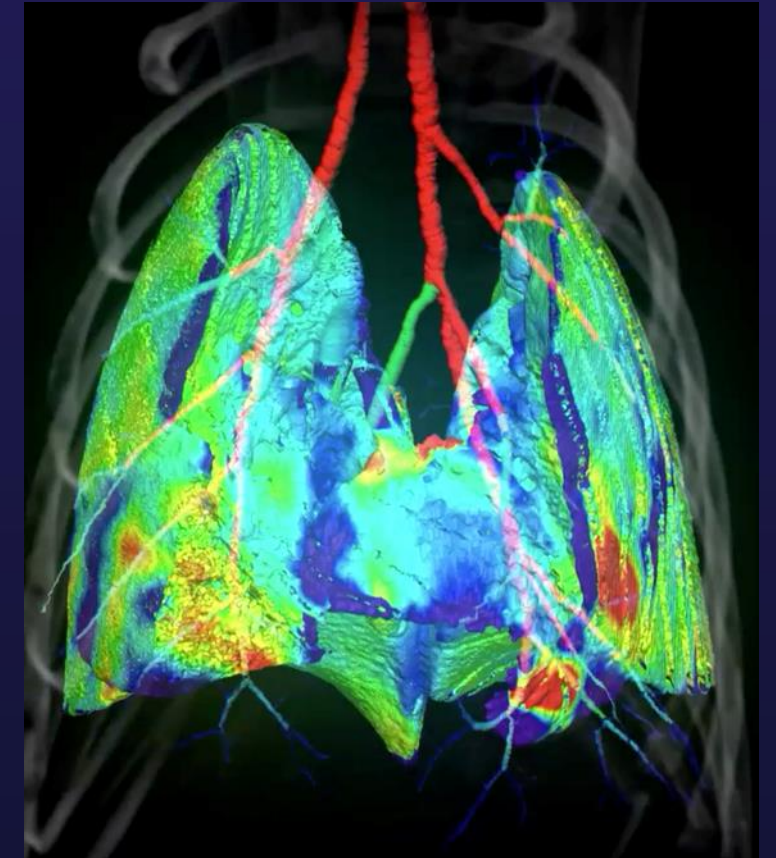
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# Executive summary

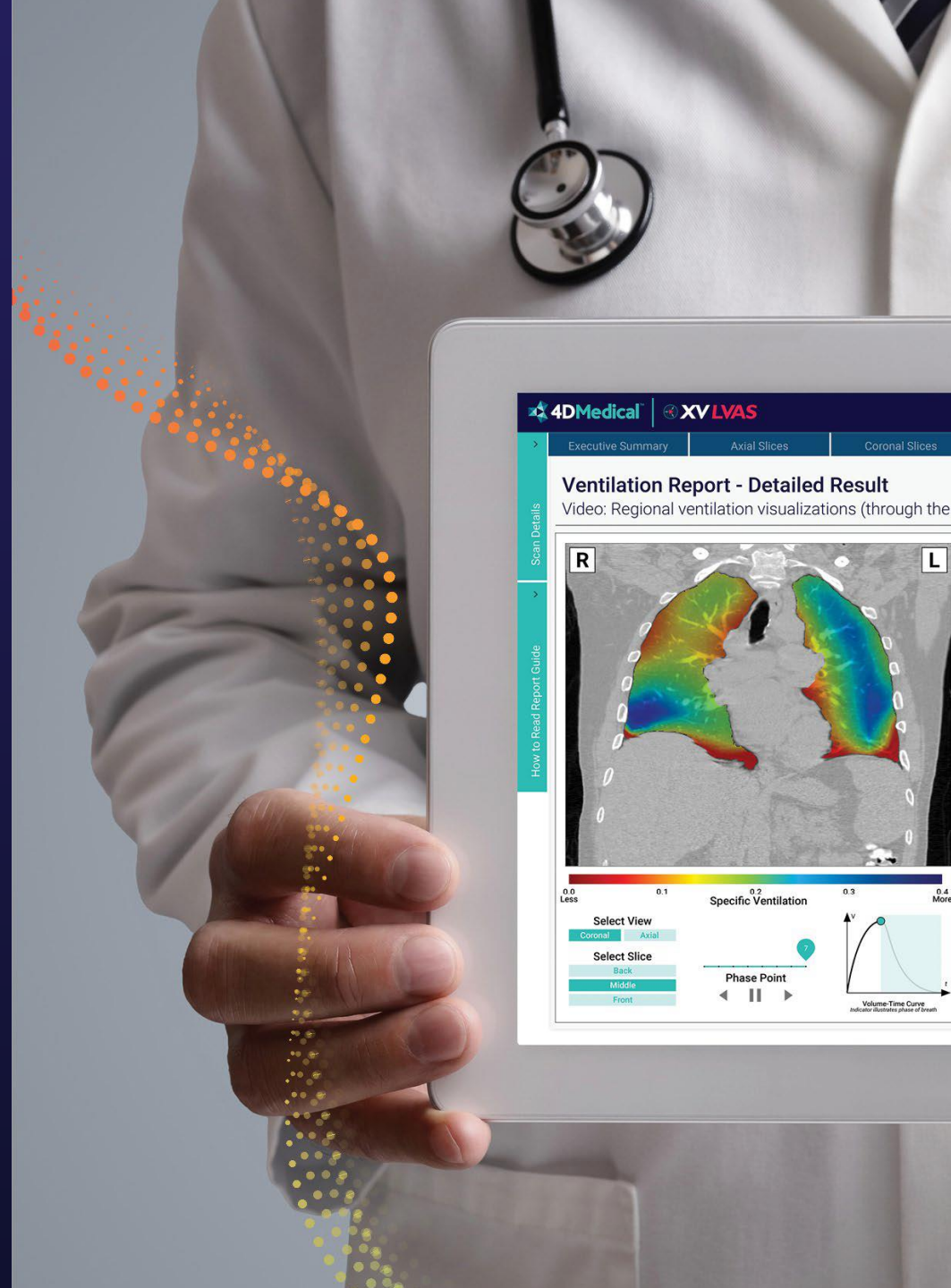
- Founded in 2012, 4DMedical is a Melbourne-based healthcare technology company focused on commercialising its patented **lung imaging platform – XV Technology™**
- 4DMedical is currently progressing the global rollout of its XV Lung Ventilation Analysis Software (XV LVAS™), which has **received FDA 510(k) clearance and TGA approval**
- **Australian Lung Health Initiative Pty Ltd (ALHI), a consortium incorporated and led by 4DMedical, has been awarded \$28.9m in funding over the next five years** under the Federal Government's Medical Research Future Fund (MRFF) Frontier initiative
- The MRFF Frontier funding will be used by ALHI to progress the development of the **world's first dedicated lung function scanner (XVD Scanner™)**, integrated with XV Technology, to provide low dose, contrast free rapid lung analysis for adults and children
- Under an agreement with ALHI, **4DMedical has been granted exclusive rights to commercialise XVD Scanners worldwide and will receive 100% of the revenue** generated from hardware sales, as well as software revenue derived from the use of XV LVAS to complete scans
- 4DMedical believes the commercialisation of XVD Scanners will **accelerate the adoption of XV LVAS at medical institutions and become a significant driver of software revenue in the future**
- The Company is undertaking a capital raising by way of **Placement and Share Purchase Plan (SPP) to raise approximately \$43.0m** to primarily fund, in conjunction with the \$28.9m of MRFF funding, the development and commercialisation of XVD Scanners
- **Capital raising proceeds will also be used to provide balance sheet flexibility** to pursue identified growth opportunities that have the potential to accelerate the commercialisation of the Company's XV LVAS solution

## XV Technology™



# Agenda

- i. Overview of ALHI
- ii. XVD Scanners
- iii. Capital Raising Details
- iv. Appendix



# Overview of ALHI

*A new frontier for respiratory diagnostics*



# ALHI & MRFF Frontier funding

## ALHI has been awarded \$28.9m of funding over the next five years under the MRFF Frontier initiative

- Australian Lung Health Initiative Pty Ltd (ALHI) is a joint venture between 4DMedical, the University of Adelaide and the South Australian Health and Medical Research Institute, that was established to deliver innovative advancements in functional lung analysis
- The MRFF Frontier Health and Medical Research initiative is an Australian Government program that provides funding for groundbreaking medical research and development under a two-stage competitive process
- ALHI was previously awarded approximately \$1.1m of funding under Stage One of the MRFF Frontier initiative to develop a detailed research plan and explore feasibility of a transformative research project to deliver groundbreaking lung health assessment tools that could impact on a global scale
- ALHI has subsequently been awarded \$28.9m of funding under MRFF Frontier Stage Two to implement its research plan and commence the development of the world's first dedicated lung function scanner (XVD Scanner)
- XVD Scanners will fulfill a critical need for safe, accurate and sensitive lung health assessment tools for both adult and paediatric patients with lung disease, by providing richer lung function data than existing modalities



# ALHI structure & partners

- ALHI is a consortium incorporated and led by 4DMedical with support from global leaders in the medical field
- 4DMedical has been granted the right to commercialise XVD Scanners and will receive 100% of revenue from XVD Scanner hardware, SaaS sales generated from the use of XV LVAS to complete scans and associated service revenue

## ALHI partners



MRFF Grant Applicant	✓	✓	✓		
ALHI Research Partner	✓	✓	✓		
ALHI Contract Research Provider	✓			✓	✓
ALHI Industry Partner	✓				
ALHI Commercialisation Partner	✓				

# Strong support from key opinion leaders



“[This program] will provide, for the first time, rapid detailed and safe assessment of lung disease, enable new preventative treatment opportunities, and allow for regular monitoring of disease and treatment progression.”

**Mark Brooke**  
CEO, Lung Foundation  
Australia



“...having recently seen the ... developments during Stage One we are even more excited by the obvious potential of this technology and its capability for use on diagnosing and monitoring CF lung disease.

We are also keen to participate in the Reference Group as it is vital to provide patient centric advice on relevant healthcare policy to the ALHI.”

**Nettie Burke**  
CEO, Cystic  
Fibrosis Australia



“The proposed research partnership offers a unique opportunity to undertake world-leading research and clinical application in respiratory medicine, with the clear potential to transform the health of children and adults with severe respiratory disease such as cystic fibrosis, chronic lung disease of prematurity and acute lung injury.”

**Prof Sarath Ranganathan**  
*MBChB MRCP MRCPC FRACP PhD ATSF*  
Director of Respiratory  
Medicine, The Royal Children's  
Hospital Melbourne



“[This program] has the ability to change the lives of people with Asthma.”

**Michele Goldman**  
CEO, Asthma Australia

# XVD Scanners

*The first dedicated lung function scanner:  
high-throughput, very low dose and greater scanning flexibility*

# Introduction to XVD Scanners

- ALHI will deliver two generations of dedicated lung function scanners (Gen 1 & Gen 2) developed without the limitations of existing infrastructure:
  - Higher detail and greater accuracy than existing modalities
  - Radiation dose less than 1 Chest X-ray for Gen 1 and 0.1 Chest X-ray for Gen 2
  - Rapid, automated scan complete in less than 10 seconds
  - No contrast agents injected or inhaled
- XVD Scanners will lead to better unit economics for medical institutions by combining rapid throughput, broader patient populations and increasing scanning frequency of individual patients due to low radiation dose
- 4DMedical's proprietary XV LVAS offering will be integrated and used by XVD Scanners to provide rapid and enhanced respiratory imaging and analysis
- XV LVAS will continue to be the focus of 4DMedical's commercialisation strategy, with XVD Scanners assisting to drive the adoption of XV LVAS and provide flexibility in pricing and custom bundle solutions for medical institutions

## Gen 1 XVD Scanner concept developed under MRFF Frontier Stage One

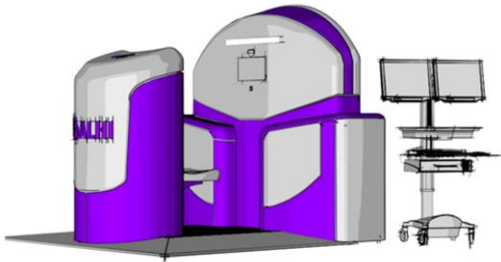




# Generation one & two development

ALHI will develop two generations of XVD Scanners that will each deliver reduced risk and increased reward

## Generation One

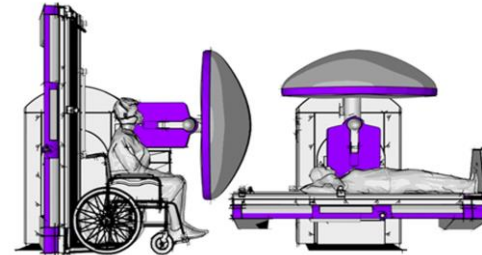


Gen 1 commence commercialisation expected in 2023

### Gen 1 features

- Dose <1 chest X-ray
- Allows first ever access to lung function measures for children and very unwell
- Walk in or wheelchair access
- Patient interaction & entertainment system
- Patient positioning system
- Breath synchronisation
- Standard X-ray (& fluoro) mode option
- Installed in room or vehicle
- Indicative RRP: A\$650,000

## Generation Two



Gen 2 commence commercialisation expected in 2025

### Gen 2 features:

- Dose <0.1 chest X-ray
- Lying down, walk in or wheelchair access
- Real-time report
- Structural imaging (via tomosynthesis)
- FEV1 mode for enhanced sensitivity
- Supports VQ (Perfusion) as well as XV (Ventilation)
- Indicative RRP: A\$900,000

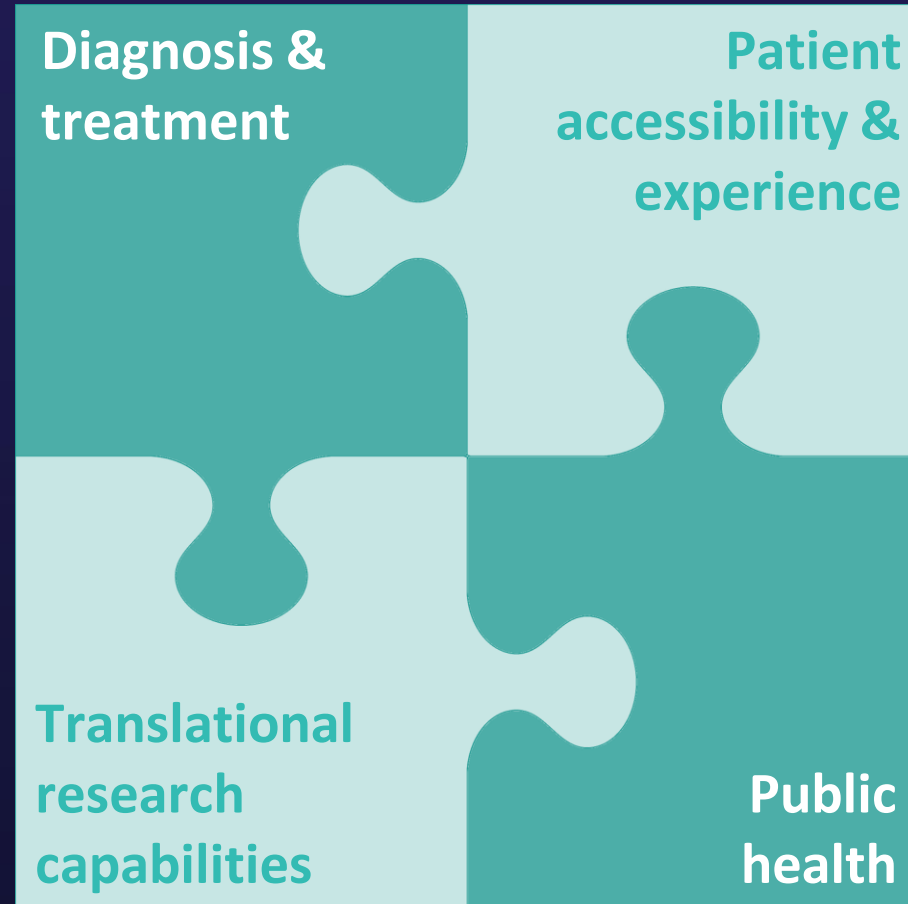
# Primary customers & use cases

## 4DMedical is responsible for global sales and marketing of XVD Scanners in the field of lung health

- 4DMedical will receive 100% of revenue from XVD Scanner hardware sales, XV LVAS software sales, and associated service revenue
- 4DMedical has developed an XVD Scanner sales strategy that will initially aim to target the following customers:
  - Globally recognised medical institutions looking to enhance their existing infrastructure portfolio with innovative technology
  - XV LVAS customers requiring greater scanning throughput
- Through the integration with XV LVAS, XVD Scanners will have both inpatient and outpatient use cases for:
  - **Diagnostic reporting:** providing lung function quantification to help demine initial treatments (i.e. ICU admission)
  - **Mass screening programs:** faster feedback on treatment efficiency enabling clinicians to make faster decisions on patient care
  - **Follow-up tool:** detailed monitoring of patients without safety concerns of excessive radiation exposure
- Future Gen 2 features will include options for embedded XV Technology for real-time analysis (enabling biosecurity application), new regional pulmonary function test modes, reduced dosage and the ability to scan patients on ventilator support

# Multi-dimensional healthcare impact

- Earlier diagnosis
  - Richer and more sensitive data
- Data-driven personalised treatments
- Monitoring of disease progression
  
- Improved understanding of respiratory diseases
- Preclinical XV Technology platform
- Clinical XV Technology platform



- Lung function assessment for children
- Flexible: standing, seated, ICU bed
- Improved physical access
- Transportable to remote locations
  
- Reduced burden on health system
- Equitable service access
- Screening programs: infectious diseases, occupational health, etc.

# 4DMedical licensing & revenue model

- 4DMedical will receive 100% of revenue generated from XVD Scanners and has allowed for a ~2% royalty of net hardware sales once commercialised
- 4DMedical has been granted the exclusive rights to:
  - Manufacture all project outputs (including XVD Scanners)
  - Market and sell XVD Scanners globally
  - All intellectual property developed by the project
- Indicative pricing model:
  - Hardware RRP: A\$650,000 for Gen 1 and A\$900,000 for Gen 2 (includes installation, training and 12-month warranty)
  - XV LVAS scans will be charged at market price
  - Estimated service revenue of ~12% of the hardware RRP p.a.
- XVD Scanners have the potential to generate software revenue of 3-5x hardware RRP over its operational life

## 4DMedical Indicative Return on first 10 XVD Scanners<sup>1</sup>

	Gen 1	Gen 2
XVD Scanners Sold	10	10
Upfront Hardware Revenue	A\$6.5m	A\$9.0m
Manufacturing Cost (inc. royalty)	A\$5.0m	A\$6.3m
No. XV Scans Completed with XVD Scanners p.a. <sup>2</sup>	52,800	98,560
Price per XV Scan <sup>3</sup>	A\$150	A\$150
XV Scan Software Revenue (over 3 years)	A\$23.8m	A\$44.4m
XV Scan COGS (over 3 years)	A\$0.5m	A\$1.0m
<b>Total Revenue</b>	<b>A\$30.3m</b>	<b>A\$53.4m</b>
<b>Total Gross Margin</b>	<b>\$24.7m</b>	<b>\$46.1m</b>

*Notes:*

1. Excludes maintenance and support revenue;
2. Indicative XV Scans for a high-volume site; and
3. Indicative XV LVAS pricing for Australian market.



# Research & regulatory pathway

## Project funding

- MRFF funding will cover the majority of R&D and the first regulatory clearance for XVD Scanners – e.g. FDA 510(k)
- 4DMedical will be responsible for funding the commercialisation of XVD Scanners and additional regulatory approvals – e.g. TGA approval

## Clinical validation

- The development pathway for XVD Scanners will include clinical trials across ~7 sites over the next five years
- 4DMedical will facilitate the day-to-day management of all clinical trials

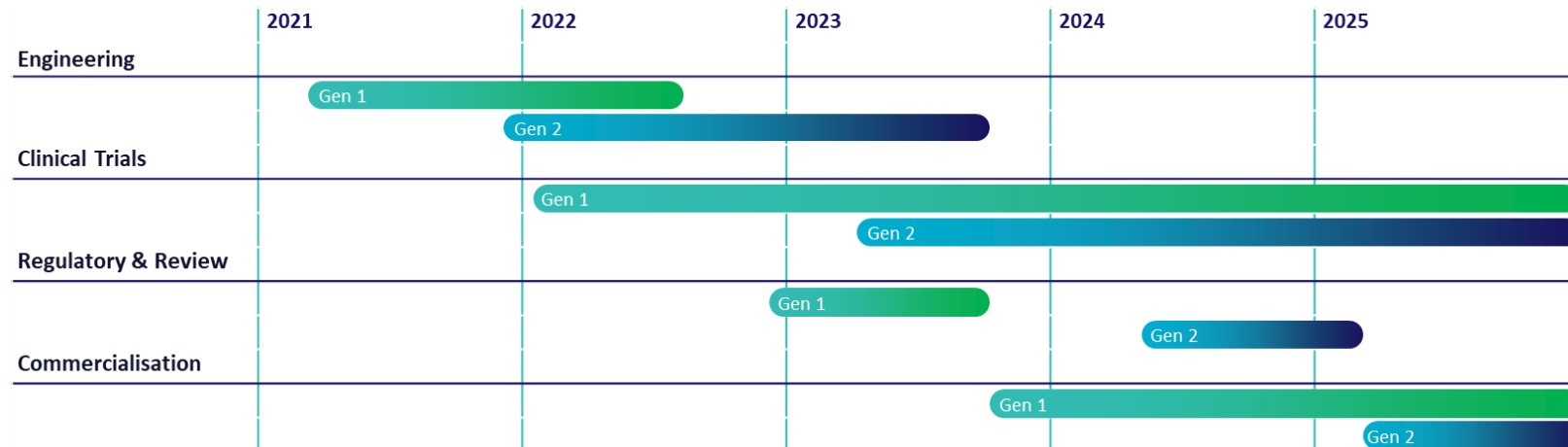
## Key opinion leaders (KOLs) support

- Prototype XVD Scanners will be allocated to high profile medical institutions globally with guidance from Key Opinion Leaders (KOLs)
- KOLs will be responsible for the publication and amplification of trial results

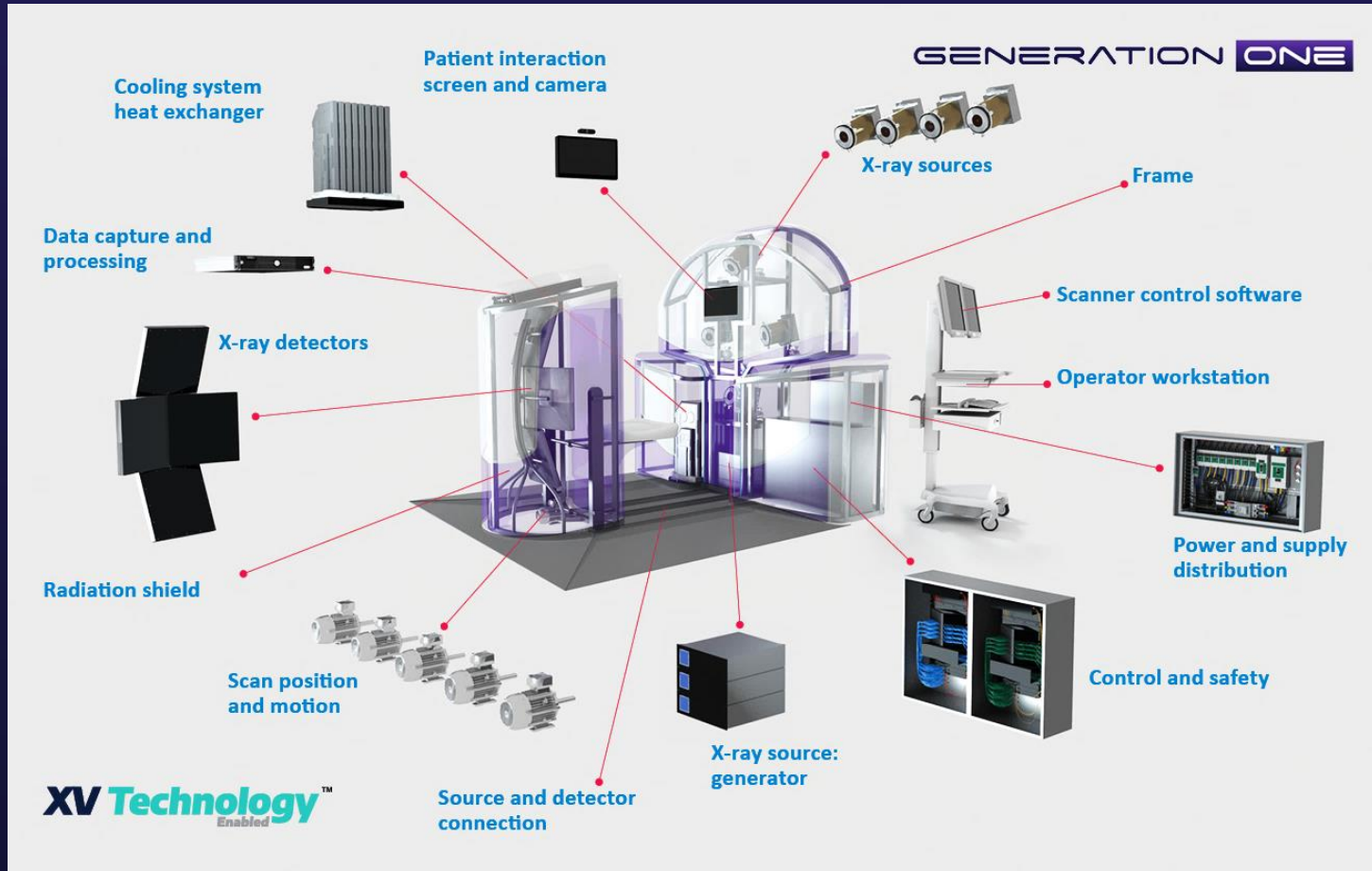
## Pipeline products

- 4DMedical has the exclusive right to all IP arising from ALHI’s activities
- This includes IP developed inside or outside the specialist area of lung imaging systems

## XVD Scanner expected commercialisation milestones



# Manufacturing & components



- 4DMedical is currently renting a ~1,700m<sup>2</sup> facility near its Melbourne headquarters where it will conduct R&D, manufacturing and testing of XVD Scanners
- The facility will have the capacity to support 4DMedical's existing XV Technology activities, as well as the concurrent ideation, prototyping and the early stages of commercial production of XVD Scanners

# Capital Raising Details

# Indicative offer details

<b>Placement</b>	<ul style="list-style-type: none"><li>• Placement to institutions, sophisticated and professional investors to raise approximately A\$40.0 million via the issue of approximately 25.8 million shares</li><li>• Placement under the Company's existing 15% Placement capacity under ASX Listing Rule 7.1</li></ul>
<b>Pricing</b>	<ul style="list-style-type: none"><li>• The Issue Price of A\$1.55 per share represents a:<ul style="list-style-type: none"><li>• 10.4% discount to the last close (A\$1.73)</li><li>• 9.9% discount to the 5-day VWAP (A\$1.72)</li><li>• 22.8% discount to the 30-day VWAP (A\$2.01)</li></ul></li></ul>
<b>Share Purchase Plan</b>	<ul style="list-style-type: none"><li>• 4DMedical intends to offer eligible shareholders an opportunity to subscribe for up to A\$30,000 of new shares under a Share Purchase Plan (SPP) at the same price as the Placement</li><li>• It is intended the SPP will be capped at approximately A\$3 million</li></ul>
<b>Use of Funds</b>	<ul style="list-style-type: none"><li>• Funds raised will be used primarily to fund, in conjunction with the \$28.9m received from Federal Government's MRFF Frontier initiative, the development and commercialisation of XVD Scanners</li><li>• Funds will also be used to provide balance sheet flexibility to pursue identified growth opportunities that have the potential to accelerate the commercialisation of the Company's XV LVAS</li></ul>
<b>Joint Lead Managers</b>	<ul style="list-style-type: none"><li>• Bell Potter Securities Limited &amp; E&amp;P Corporate Advisory Pty Limited</li></ul>



# Timetable

<b>Trading halt following award of MRFF grant</b>	Friday, 26 February 2021
<b>Company enters suspension for capital raising</b>	Tuesday 2, March 2021
<b>Transaction announced &amp; Company resumes trading</b>	Thursday, 4 March 2021
<b>Settlement of new Placement shares</b>	Wednesday, 10 March 2021
<b>Allotment of new Placement shares</b>	Thursday, 11 March 2021

# Appendix

# Global lung diagnostics market opportunity

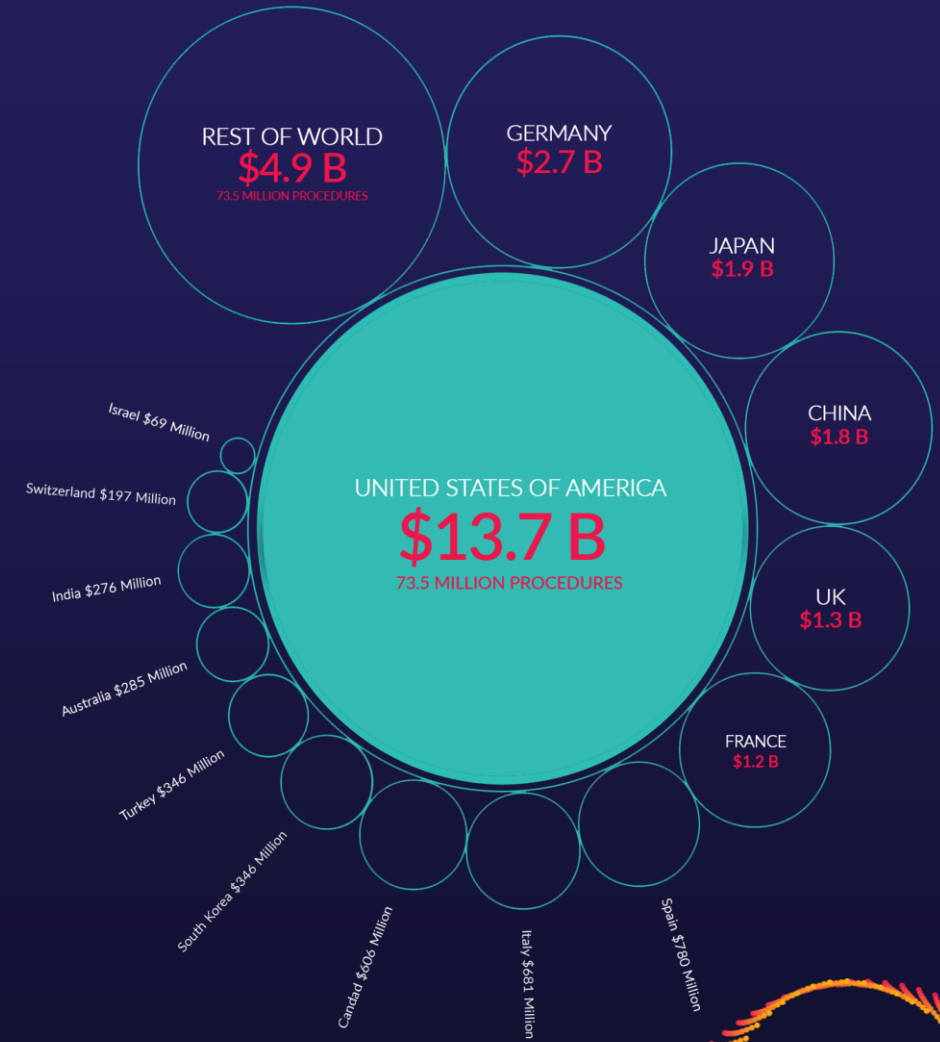
4DMedical considers its market opportunity to be supplementing or replacing existing respiratory diagnostic modalities.

In 2019, more than US\$31 billion was spent on respiratory diagnostics across more than 377 million procedures globally.

In the US, 4DMedical’s key market, more than US\$13.7 billion was spent across more than 73 million procedures.

By comparison, the Australian market spent US\$285 million on respiratory diagnostics across more than 5 million procedures.

Country	Spend (US\$m)	Procedures (m)
US	13,716	73.5
Rest of World	4,964	59.8
Germany	2,678	20.3
Japan	1,905	22.8
China	1,851	101.6
UK	1,351	8.9
France	1,191	10.2
Spain	780	8.4
Italy	681	8.5
Canada	606	8.0
South Korea	450	6.8
Turkey	346	16.1
Australia	285	5.3
India	276	25.3
Switzerland	197	1.2
Israel	69	1.1
<b>Total</b>	<b>31,346</b>	<b>378</b>



# The current modality gap

Current best practice respiratory diagnostics are decades out of date, not fit for purpose and are ripe for displacement. While each provides important insights, they often detect lung disease too late for effective treatment. Their limitations leave both doctors and patients in the dark.

Approximately 98% of all lung diagnostic procedures globally are made up of spirometry, X-ray and computed tomography (CT)

## Spirometry – 1846

1-dimensional technology  
Accurate but insensitive



Spirometry is the current benchmark in lung diagnostics, but it can only measure pulmonary capacity as an average over the entire lung.

Average estimated cost  
Spirometry = US\$72  
Pulmonary Function Test = US\$750

## X-ray – 1895

2-dimensional technology  
Inexpensive but inconclusive

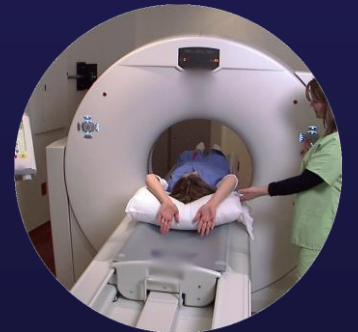


X-rays are widely accessible, inexpensive and emit low radiation, but its results are clinically limited, non-functional and inconclusive.

Average estimated cost = US\$120

## CT – 1971

3-dimensional technology  
Sensitive but expensive and high radiation



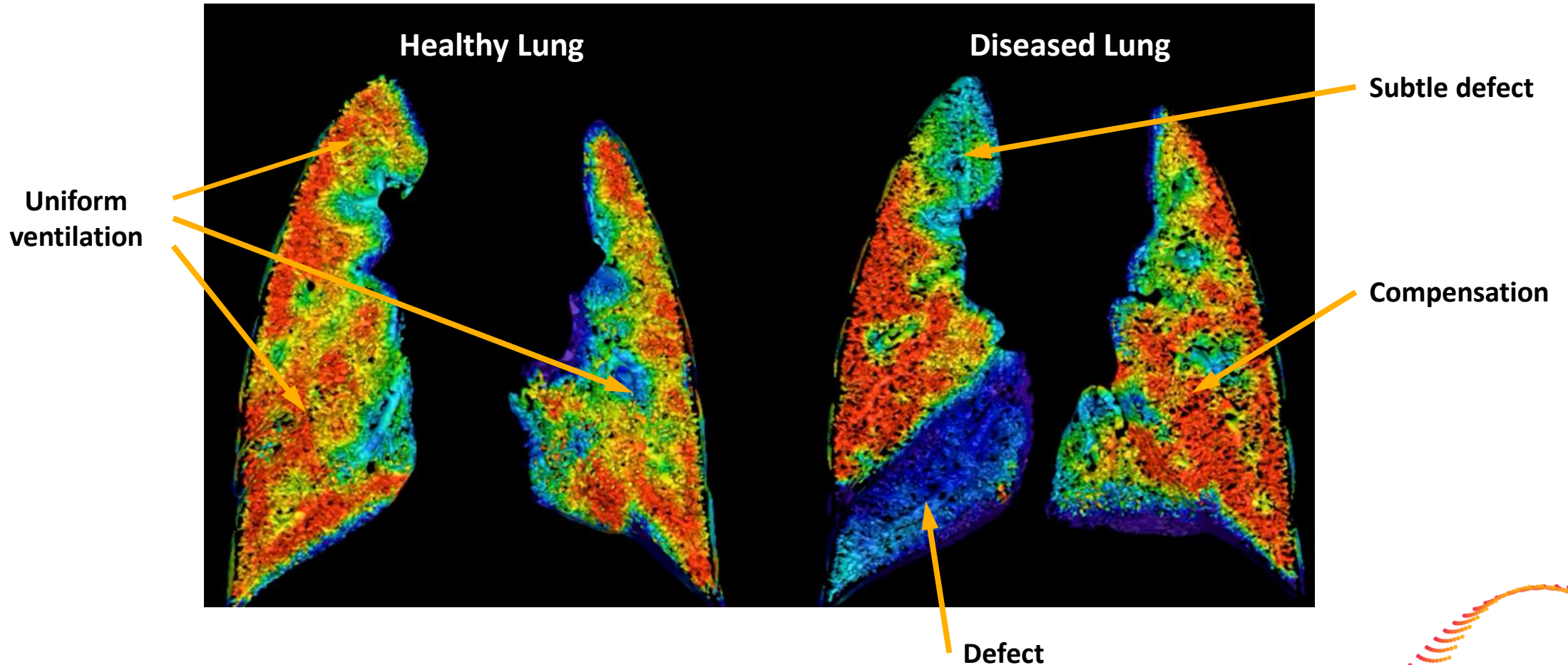
The current gold standard for determining underlying lung structure, but is high cost, requires a skilled radiologist and delivers 70x radiation dose of a chest X-ray.

Average estimated cost = US\$525



# XV Technology™ combines the best features of existing modalities

1) Functional insight of spirometry at a regional level; 2) comparable radiation dose to X-ray; and 3) high-detail resolution of a CT scan

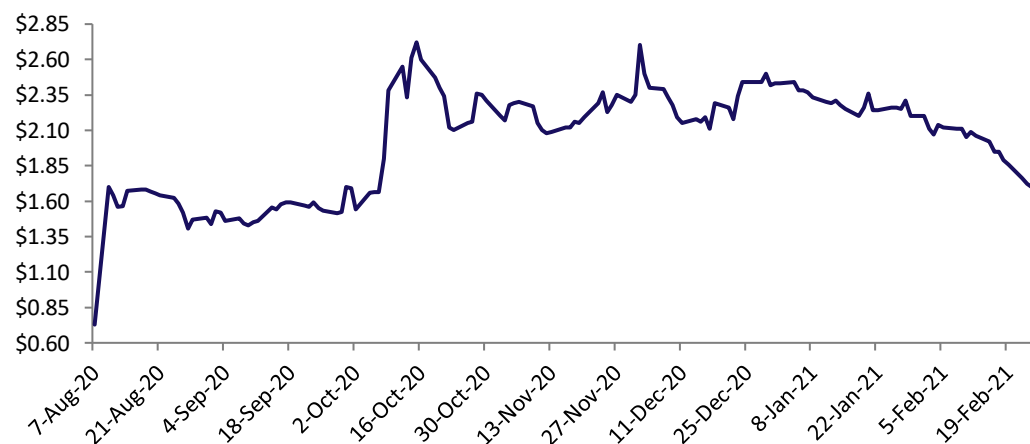


# Corporate snapshot

## Capital structure

Ticker	4DX
IPO offer price	\$0.73
Share price (25 February 2021)	\$1.73
Shares on issue (m)	264.76
Options on issue (m)	20.67
Market capitalisation	\$458.04m

## Share price



## Senior management team

Andreas Fouras	Group Managing Director & CEO
Heath Lee	Chief Financial Officer
Craige Pendleton-Browne	Chief Information Officer
Paul Cooke	SVP, Sales & Marketing
Aidan Jamison	SVP, Engineering
Jason Kirkness	VP, Medical & Clinical Affairs
Rachael Tenkaten	VP, Product
Jon Dusting	VP, Imaging Systems
Charlene Stahr	Company Secretary
Terence Walsh	Director of Quality & Regulatory Affairs
Michael Curtis	Chief Software Architect
Ming Lam	Financial Controller

# Risks

Key Risks	
<b>Sufficiency of funding</b>	The Directors consider that, on receipt of funds from the placement and SPP, 4DMedical will have sufficient working capital to carry out its objectives. However, financial resources are limited and there is a risk that 4DMedical may never achieve profitability. 4DMedical may be required to raise additional funds from time to time to finance the development and commercialisation of its products and other longer-term objectives. The ability to raise additional funding is subject to factors beyond the control of 4DMedical and its Directors. The Directors can give no assurance that future funds can be raised by the Company on favourable terms, or at all.
<b>Barrier to entry</b>	Competitors in the respiratory imaging sector may seek to minimise the ability of 4DMedical to penetrate the market by seeking to impede or disrupt 4DMedical's ability to establish product distribution and maintenance pathways. However, as a cloud-based SaaS service provider, the risk that a third party may successfully impede 4DMedical's ability to penetrate the market is reduced.
<b>Future profitability is uncertain</b>	4DMedical is not yet profitable and has historically incurred losses. 4DMedical is still in the early sales and commercialisation stage for its XV Technology. Although FDA and TGA clearance has been obtained for the XV (Ventilation) product, there is no guarantee that regulatory approval will be obtained for any of 4DMedical's other products or that regulatory approval of 4DMedical's products will guarantee market adoption of its products, which is crucial for revenue generation and profitability.
<b>Foreign exchange risk</b>	4DMedical's financial position may be negatively affected by exchange rate fluctuations. In particular, the majority of 4DMedical's costs are Australian dollar denominated relating to remuneration for R&D staff who are based in Melbourne, whereas 4DMedical's initial revenues from operations upon listing are expected to be substantially U.S. dollar denominated. 4DMedical is subject to adverse exchange movements, particularly in the USD:AUD exchange rate. This is expected to become more significant in the future as more revenue is anticipated to be generated offshore.
<b>Intellectual property risks</b>	4DMedical's success, in part, depends on its ability to obtain patents, maintain trade secret protections and operate without infringing the proprietary rights of third parties. If patents are not granted, or if granted only for limited claims, 4DMedical's intellectual property may not be adequately protected and other third parties may be able to copy or reproduce 4DMedical's intellectual property. 4DMedical has developed and owns a range of proprietary items of intellectual property that management believe are novel and inventive. The granting of a patent does not guarantee that the rights of others are not infringed or that competitors will not develop technology to avoid the patented technology.

# Risks

Key Risks	
<b>Key personnel risk</b>	The successful operation of 4DMedical in part relies on 4DMedical's ability to retain its existing key management personnel who have intimate knowledge of the business and its products. The loss of any key members of management or the inability to attract additional skilled individuals to key management roles, may adversely affect 4DMedical's capacity to develop and implement its business strategies.
<b>Changes in law risk</b>	The legislative frameworks in key countries may vary without notice and adversely impact 4DMedical's operations and profitability. Failure by 4DMedical to comply with legislative or regulatory requirements may result in compliance orders being issued against 4DMedical, financial penalties being levied against 4DMedical, a cessation of its operations or reputational damage.
<b>Regulatory risk</b>	There is a risk that regulatory bodies will not grant 4DMedical regulatory clearance to market its products or will significantly delay the grant of such clearances. Failure to receive regulatory clearance will have a negative impact on 4DMedical's future revenue streams. In addition, changes to regulatory regimes may become more burdensome in the future. If this occurs, 4DMedical may be required to dedicate more time and resources to ensuring that it complies with these regulations, which could adversely affect its financial performance and future prospects.
<b>Risk of superseding technology and competition from new entrants</b>	There is a risk that new technology will be developed that will supersede 4DMedical's technology. Although new technologies have significant development and commercialisation times, 4DMedical cannot guarantee that its technology will not be superseded by a competitor. 4DMedical's potential competitors may include companies with substantially greater resources and access to more markets. Therefore, competitors may succeed in developing products that are more effective or otherwise commercially superior to 4DMedical's products.
<b>Technology supplier risk</b>	There is a risk that 4DMedical's cloud delivery supplier could breach the delivery agreement or another relevant contractual arrangement and that 4DMedical would be required to replace its supplier. A significant interruption to 4DMedical's ability to deliver its SaaS product could adversely impact its business, operating results and financial performance. Further, 4DMedical currently relies on software licensed from Laurel Bridge Software Inc to enable PACS to PACS workflow via the software. If 4DMedical's ability to rely on the software is compromised, then its ability to service U.S. based customers would be impacted.
<b>Product liability</b>	There are no assurances that there will not be unforeseen performance characteristics or defects arising in relation to 4DMedical's products. Adverse events relating to its products could expose 4DMedical to product liability claims, litigation or the removal of its regulatory approvals. Product liability claims also have the potential to damage 4DMedical's reputation and the ongoing viability of 4DMedical if there is a significant erosion in the reputation of 4DMedical.

# Risks

Key Risks	
<b>4DMedical's business may not achieve its intended goals</b>	There is a risk that 4DMedical may fail to achieve commercialisation and distribution goals. 4DMedical technology needs to find acceptance in a competitive market. Market acceptance depends on numerous factors (including convincing potential consumers and partners of the attractiveness of 4DMedical's products).
<b>Future acquisitions</b>	4DMedical may seek to acquire businesses or companies to achieve its objectives. There is a risk that any due diligence investigations undertaken by 4DMedical will not identify issues which are material to the acquisition and which could result in additional liabilities affecting 4DMedical.
<b>Privacy risk</b>	4DMedical seeks to ensure that it has appropriate security measures and risk management systems in place to maintain the confidentiality and privacy of personal information collected from its customers, end-user patients, employees and others. However, those security measures are subject to various risks (including computer viruses, electronic theft, physical damage, third party provider failures or similar disruptions). The failure of 4DMedical to maintain the confidentiality of this information could breach law and cause significant operational, financial and reputational damage.
<b>Contract risk</b>	<p>4DMedical expects the formal grant agreement will be finalised and executed with the Commonwealth as soon as practicable. 4DMedical has been provided with a template of the proposed form of agreement (which incorporates the Commonwealth Standard Grant Conditions) and expects the final agreement to be substantially in that form (Template Agreement). In this context, 4DMedical anticipates that ALHI will be:</p> <ul style="list-style-type: none"> <li>• subject to reporting obligations throughout the life of the grant, in order to meet the Commonwealth's expectations as to the development of the XVD Scanner, use of funds, compliance with agreed budgets, and ALHI meeting other agreed milestones;</li> <li>• receiving grant monies on a periodic basis subject to ALHI satisfying the Commonwealth's progress expectations and meeting key payment triggers; and</li> <li>• providing the Commonwealth a permanent, non-exclusive, irrevocable, royalty-free licence to use, modify, communicate, reproduce, publish and adapt any material (including documents, hardware, software and data) created or developed by ALHI as a result of the grant (including certain existing material associated with the activity the subject of the grant).</li> </ul> <p>Under the Template Agreement, the Commonwealth has the right, acting reasonably, to cancel or reduce the scope of the grant, including, for example, due to a change of government policy. The Commonwealth will also have the right to reduce, suspend or terminate the grant if ALHI does not comply with its obligations under the grant or fails to remedy a breach, in which case there is a risk that the Commonwealth may seek repayment of funds advanced under the grant.</p>
<b>General risks related to an investment in 4DMedical securities</b>	A number of general risks related to investing in securities issued by 4DMedical are included in Section 5.2 of the Prospectus issued by the Company at IPO.



# Contacts

## Corporate

Charlene Stahr

Company Secretary

[companysecretary@4dmedical.com](mailto:companysecretary@4dmedical.com)

## Investor Relations

Simon Hinsley

+61 401 809 653

[shinsley@4dmedical.com](mailto:shinsley@4dmedical.com)

## Media

Matthew Wright

+61 451 896 420

[matt@nwrcommunications.com.au](mailto:matt@nwrcommunications.com.au)

For more information please visit [www.4DMedical.com](http://www.4DMedical.com)



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