

## Goldman Sachs Healthcare IT Series

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ASX: 4DX

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## **Executive summary**

4DMedical is a software company creating a step change in the capacity of physicians to diagnose and manage patients with lung disease via its four-dimensional lung imaging platform - XV Technology™

- Focused on commercialising our flagship XV Lung Ventilation Analysis Software (XV LVAS™), which utilises mathematical models and algorithms to convert X-ray images into quantitative scan data
- Clinically validated to provide non-invasive analysis of regional lung motion and airflow in real-time

## Global respiratory diagnostic market represents a ~US\$31 billion per annum opportunity

- Approximately 377 million respiratory diagnostics tests performed per annum globally
- Existing lung diagnostics are decades out of date, not fit for purpose and ripe for displacement
- Initial focus on the U.S. respiratory diagnostic market worth US\$13.7 billion per annum

## Company is well funded to execute on commercialisation strategy

- Offering is focused on improving hospital and patient outcomes with limited capex requirements
- Capital light business model with rapid SaaS deployment expected >90% gross margin
- Significant barriers to entry: first mover, strong IP portfolio and advanced product pipeline
- Strong balance sheet, with A\$60.2m cash in bank as at 31 December 2021





# Respiratory Diagnostics Market Overview

## ~US\$31 billion global lung diagnostics market opportunity ripe for disruption

- Initial focus is on penetrating the U.S. and Australian markets representing a US\$13.7bn and US\$285m opportunity respectively
- Given the large market size, even low market penetration could lead to substantial revenue generation with high gross margin
- Respiratory diagnostic technologies are out of date having made insignificant advancements over the last 50 years
- Approximately 99% of all lung diagnostics are made up of thoracic X-ray, thoracic CT, PFTs and nuclear medicine
- Current diagnostics trade off accuracy, sensitivity, cost and radiation exposure, while failing to provide a comprehensive insight into the form and function of the patient's lungs

## Global lung diagnostics market

Computed Tomography (CT)

Procedures

44.5m

**Expenditur** 

US\$11.9bn

Nuclear Medicine

Procedures

1.4m
Expenditure
US\$1.6bn

Pulmonary Function Tests

Procedures

78.9m

Expenditure

US\$3.4bn

X-ray Technology

Procedure

253.0m

Expenditure

US\$14.5bn



## Spirometry & PFT

## Accurate but insensitive

#### Overview

- Invented in 1846
- 1-dimensional technology
- Current benchmark in lung diagnostics
- #2 lung diagnostic in U.S. with ~12.2m tests performed in 2019 (~17% of all lung diagnostic procedures)



## Average estimated cost\*

Spirometry: US\$72

Complete PFT: US\$750

# Pre Track Pre Track

### **Advantages**

- Functional
- Accurate
- Zero dose
- Non-invasive
- Low cost (Spirometry)

#### Limitations

- Insensitive (quantifies the whole of lung as one averaged measure)
- Non-specific: requires 20% variance to be clinically significant resulting in late diagnosis
- Complete PFT expensive and time consuming
- Effort dependent (repeatability issues)
- Not applicable to all patient cohorts

## X-ray technology

Inexpensive, but tells us very little about airflow

#### Overview

- Invented in 1895
- 2-dimensional technology
- Widely used in clinics to determine changes in lung structure
- #1 lung diagnostic in U.S. with ~49.6m tests performed in 2019 (~67% of all lung diagnostic procedures)





## Average estimated cost\*

• US\$120

## Advantages

- 2-dimensional scan
- Ubiquitous
- Relatively inexpensive
- Low radiation dosage (0.1 mSv)

## Limitations

- Measures structure rather than function
- Limited clinical value
- Overlapping anatomy means features can be hidden and be missed
- Poor record in screening applications (e.g. lung cancer, and occupational diseases)



## Computed Tomography (CT)

## Sensitive, but expensive and high radiation dose

#### Overview

- Invented in 1971
- Considered the current gold standard in lung diagnostic testing
- #3 lung diagnostic in U.S. with ~10.9m tests performed in 2019 (~15% of all lung diagnostic procedures)





## Average estimated cost\*

US\$525

## **Advantages**

- 3-dimensional scan (can't miss features)
- Sensitive
- High-resolution detail of images

#### Limitations

- Expensive: 4 times the cost of an X-ray
- High radiation dose: 70 times an X-ray (7 mSv); cancer risk for recuring exposure
- High rate of false positives (~95% in NLCST vs 3% mortality for surgery)
- Measures structure rather than function (requires skilled radiologist to infer function)
- Very high rate of utilisation based on availability

## Nuclear medicine

Capability to measure both ventilation and perfusion, but has significant limitations

#### Overview

- Invented in 1963
- Ventilation-perfusion (VQ) scan uses dual radioactive agents to examine airflow and blood flow in the lungs
- #4 lung diagnostic in U.S. with ~780k tests performed in 2019 (~1.1% of all lung diagnostic procedures).

## Average estimated cost\*

VQ Scan: US\$1,503

## Advantages

- Perfusion analysis capability
- Only modality that can identify ventilationperfusion mismatch
- Importance in treating pulmonary embolism & hypertension

# Sagittal 51-52 65-46 | 67-43 | 49-50 | 51-52

## Limitations

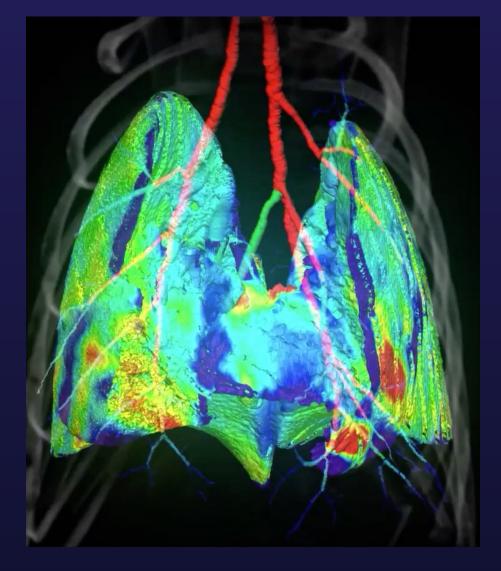
- High cost, poor resolution of outputs
- Time consuming (1 hour to complete)
- Use of dual radioactive particulate contrast agents raises toxicity concerns, particularly for those with pulmonary hypertension
- Expensive testing equipment needed
- Complex to administer, requires expert analysis, onerous safety precautions





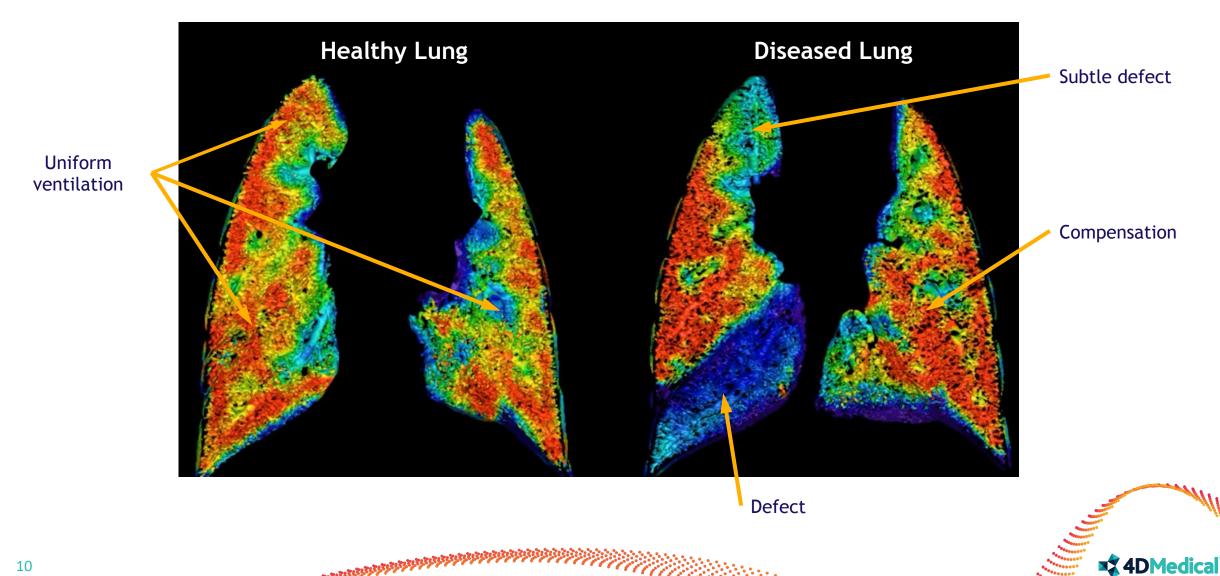
# Introducing XV Technology™

# Overview of XV Technology™





## XV Technology<sup>™</sup> demonstration



## XV Technology<sup>™</sup> clinical use case

~40 yrs underwent Treatment for a Severe Progressive Silicosis related Occupational Lung Disease.

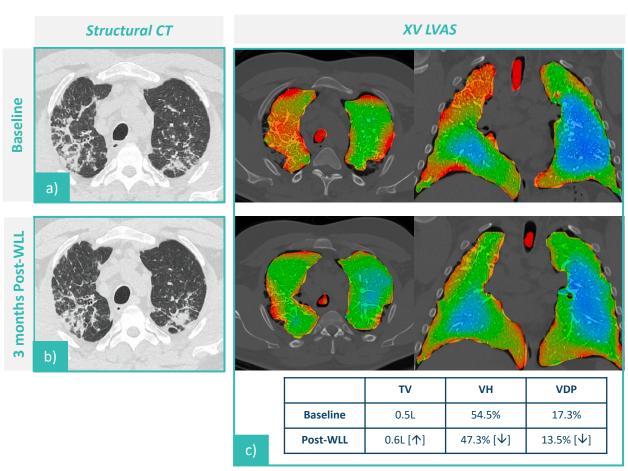
## Findings:

- a) At baseline, there are advanced changes of chronic, complicated silicosis as marked by nodular coalescence and fibrosis in the apical regions bilaterally, leading to progressive massive fibrosis.
- b) No significant structural changes are seen after treatment (on CT).
- c) Following treatment, there are functional improvements in all inspiratory metrics visible on XV LVAS. Notably, the right apical region with areas of relative underventilation (red shading) has markedly improved to average ventilation (green shading) following treatment.

## Interpretation:

Quantifiable, regional improvements in inspiratory function have been observed following treatment for lung disease, which assists the clinician in monitoring treatment effectiveness.

In comparison, serial chest CTs showed no significant change following this treatment.





## XV Technology<sup>™</sup> value proposition



Superior lung health analysis to existing modalities



Non-invasive and fast imaging protocol (~5 mins)



Earlier diagnosis provides improved patient outcomes



Seamless integration with radiology workstreams



Rapid integration (~5 days) leveraging existing hospital equipment



Cost effective for hospital with no additional capex

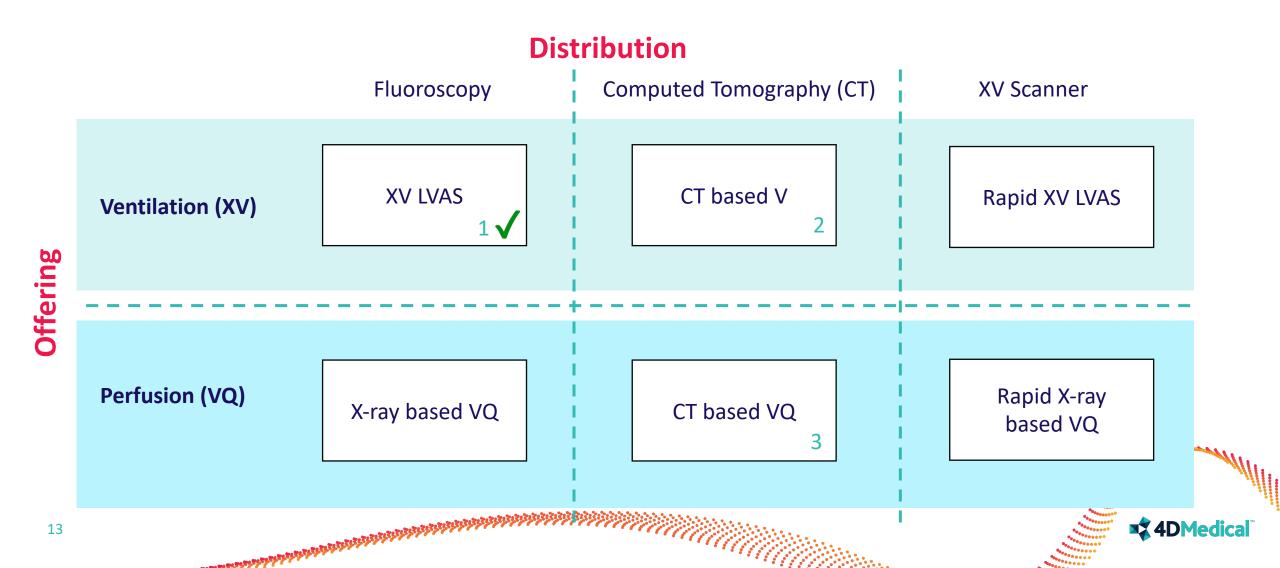


Low radiation dose and no contrast agents



## Product pipeline

**Product focus**: Simplicity of offering (i.e. Ventilation or Perfusion) with flexibility of distribution.



## Product pipeline

Successful installation of XV Scanner: World's first lung function scanner at Prince of Wales Hospital, 17 March 2022



Left to Right: **Dr Ron Shnier** (I-MED CMO), **Dr Andreas Fouras**, **Dr Jon Dusting** (4DMedical VP), Christa Brayer (Lung Foundation Australia General Manager)



Left to Right: **Dr Andreas Fouras**, **Minister Greg Hunt** (Australian Minister for Health and Aged Care)



# Commercialisation Strategy

## Commercialisation strategy

Two pillars of 4DMedical's commercialisation strategy to secure market share and scale

## Clinical trials



Research partners delivering the body of scientific evidence for clinical use

#### Who

Eminent researchers & leading medical institutes

### Why

Diagnostics, treatment efficacy, monitoring, disease progression & more

#### Outcome:

- Scientific investigation into case applications
- Publishing medical manuscripts and presenting research to industry

Study design: Full scientific method per researcher

## Clinical pilots



Physicians gaining familiarity with XV Technology and insights for patient care

#### Who

GPs, respiratory specialists, imaging centres & hospitals

## Why

Assess regional lung function for patient management

#### Outcome:

- Clinical familiarisation with XV Technology
- Feasible new use of existing X-ray equipment (imaging centres)

Pilot design: Tiered per facility & physician interest



## Commercialisation roadmap

Each strategy supports broad market adoption and uptake of XV Technology





