Investor ———— July 2018 Presentation



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# **Investment Highlights**

Large and Attractive Markets

Differentiated Advantages

Significant Body of Clinical Evidence

Regulatory Clearances

Reimbursement

- Cancer Survivorship >US\$1.8 Billion p.a.
- Chronic Heart Failure >US\$1.0 Billion p.a.
- Successfully building high margin subscription business
- Highly disruptive non-invasive technology for the clinical monitoring of tissue composition and fluid status
- Robust patent portfolio with more than 40 families
- Cloud based data of <u>all</u> patient measurements allows for proprietary analytics and algorithm optimisation
- Lymphoedema Peer-Reviewed Publications of 1,460 patients in 5 studies
- CHF Peer-Reviewed Publications of ~250 patients in 5 studies
- +400 Peer-Reviewed Publications using BIS for tissue and fluid monitoring across many chronic diseases
- FDA Clearance for the clinical assessment of lymphoedema
- FDA Clearance for monitoring patients with CHF (clinical and at-home monitoring)
- CE Mark for multiple indications including lymphoedema and CHF
- Category I CPT Code® for lymphoedema
- Existing codes for CHF and home monitoring
- Our model fits the evolving US reimbursement environment (Fee-for-Service to Value Based Medicine)

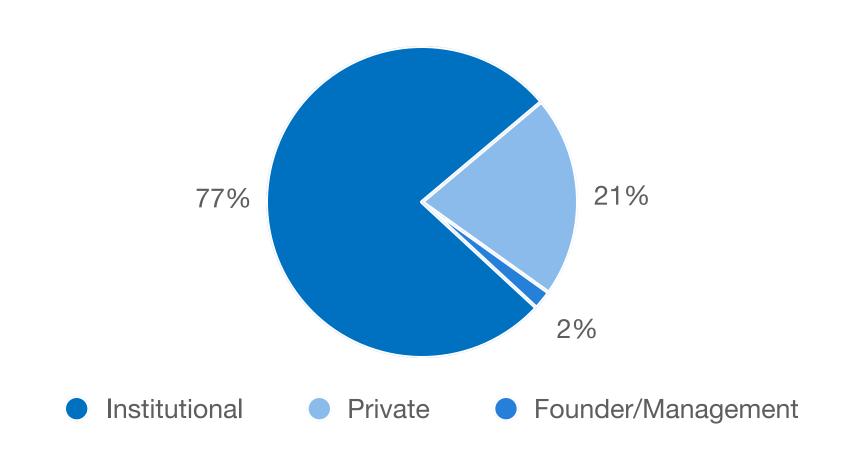
# **Corporate Overview**

- ASX listed (October 2007)
- S&P/ASX 300 added March 2015

Operations in US (San Diego, CA), Australia
 (Brisbane) and Europe (Greece) (69 total staff)

- Market capitalisation ~AU\$163M (~379M shares on issue)
- Cash on hand AU\$31.3M (30 June 2018)

#### **Share Register Breakdown**



#### **Substantial Shareholders**

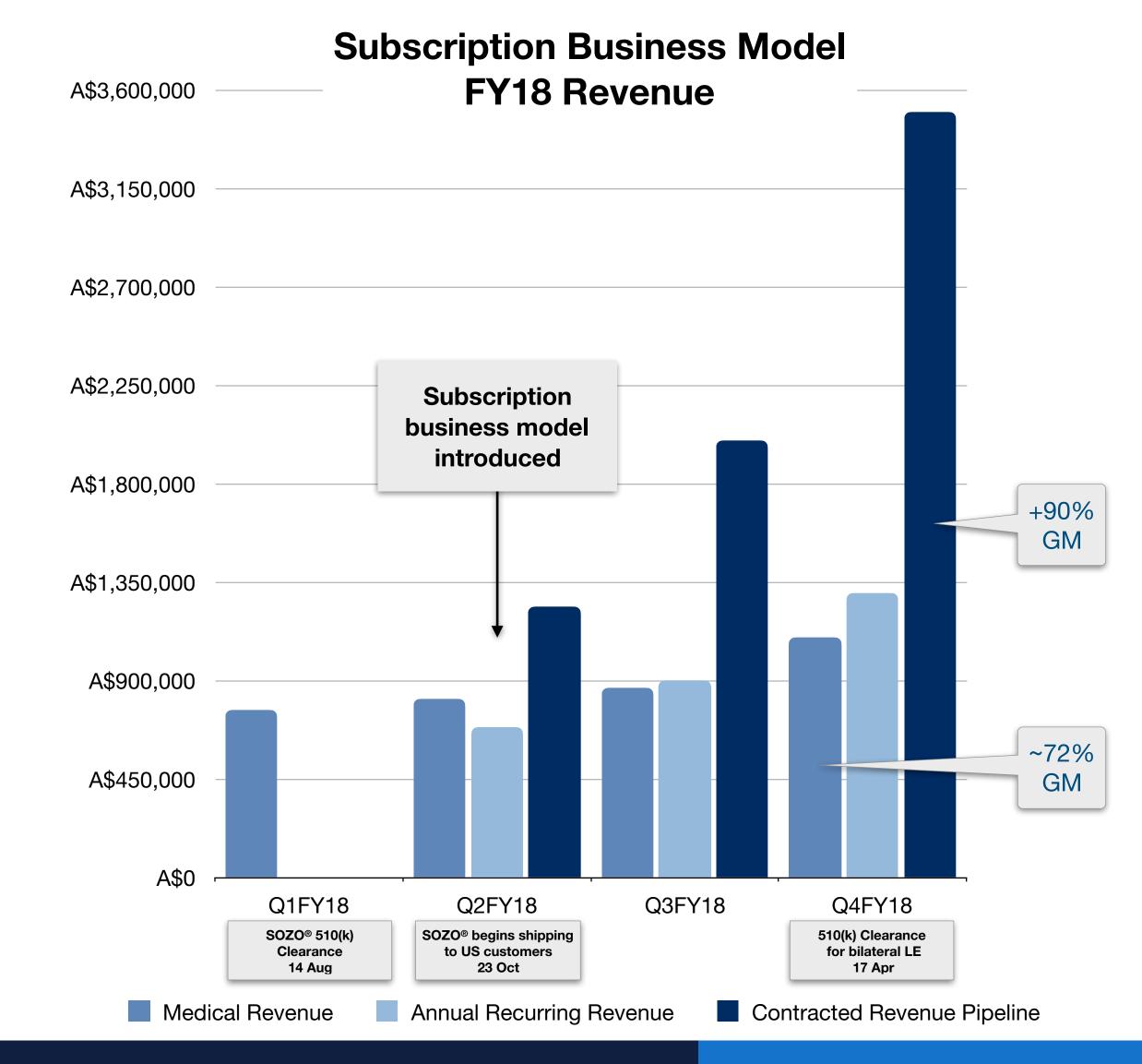
Allan Gray	17.0%
Fidelity (FIL)	7.5%
Starfish Ventures	6.8%
Kinetic Investment Partners	6.4%
Paradice Investment Management	6.1%
Macquarie Group Limited	5.1%

# **Revenue Highlights**

Key Stats (AUD \$ millions) (Preliminary and unaudited)	Q3	Q4	Change	% Change
Contracted Revenue Pipeline (CRP)	\$2.0	\$3.5	\$1.5	75%
Total Contract Value (TCV)	\$0.9	\$1.9	\$1.0	111%
Annual Recurring Revenue (ARR)	\$0.9	\$1.3	\$0.4	44%
Medical Revenue	\$0.9	\$1.1	\$0.2	22%

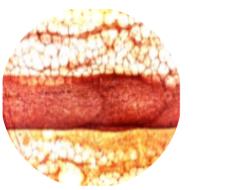
#### **Key Points**

- 1. Q2 FY18 began transitioning business to Subscription Model in conjunction with the introduction of the SOZO® Digital Health Platform
- 2. Current Medical Revenue consists of legacy products and consumables, and SOZO® units and subscription services. Blended gross margin ~72%
- 3. Contracted Revenue Pipeline (CRP) revenue consists primarily of subscription services and some amortised capital. Blended gross margin +90%
- 4. Total Contract Value (TCV) is the total value of customer contracts signed during the period including one-time and recurring revenue
- 5. Annual Recurring Revenue (ARR) is the normalised amount of revenue reasonably expected to be booked for the next 12-month period based on existing signed contracts, and assuming installation upon sale
- 6. Subscription revenue now accounts for 10% of the company's quarterly medical revenue (up from <3% in the previous quarter)

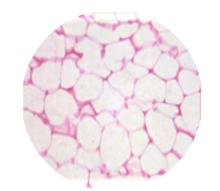


# **BIS Technology**

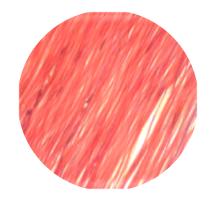
# Low Frequency Current passes around cells 256 different Frequencies Reactance (Xc) High frequency 1000 kHz High Frequency Current passes through cells Low frequency 3 kHz extrapolation extrapolation R infinity (Rinf) Resistance (R) R zero (R0)



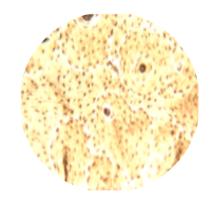
Fluid



Fat



Muscle



Bone

# **Advantages**

- Accurate
- Fast
- Sensitive
- Non-invasive
- Informative
- Actionable
- Medically meaningful

# **BIS Provides the Tools for Good Clinical Decision Making**

- Historically, it has been difficult to detect and understand the changes happening inside a patient's body over time
- The commonly used measures of weight, blood pressure, and BMI are crude, have limited information value, and are often misleading
- More precise tissue measurements (such as DEXA or CT scanning) are expensive and not suitable for routine use due to radiation exposure
- More precise fluid (intracellular and extracellular)
  measurements (such as with deuterium oxide dilution)
  are costly and extremely time consuming
- BIS is able to simply provide highly accurate and informative metrics to routinely monitor and manage the health of patients



~60% of the human body is made up of water

# **SOZO® - Next Generation BIS Digital Health Platform**

- Combines the technology of our world renowned scientific and medical devices into a single digital health platform
- Designed to easily integrate into current patient work flows
- Testing takes as little as 30 seconds
- Robust reporting capabilities
- Protocol compliance capabilities
- Ability to expand the clinical utility of the platform through simple software upgrades
- De-identified data collected for algorithm refinement
- FDA Clearances:
  - Unilateral and bilateral lymphoedema
  - Monitoring fluid in CHF patients
  - Use in medical facilities and monitoring patients at-home



# Initial Focus on Cancer Survivorship and Chronic Heart Failure

## **Cancer Survivorship**

- Cancer and its treatments have a huge impact on the body that often affects the quality of life after the disease
- 1.7M new cases of cancer and 15.5M living cancer survivors in the US
- 1 in 3 cancer survivors will develop lymphoedema as a result of their cancer treatment
- SOZO® can assist with the early detection of lymphoedema and other aspects of patient management (nutrition, bone density, muscle wasting)

Addressable Market US\$1.8 billion p.a.

## **Chronic Heart Failure (CHF)**

- CHF is a progressive disease in which patients experience a permanent decline every time they have a major cardiac event
- 6.5M CHF patients in the US of which 25% (1.6M) are classified as Class-III (moderate-to-severe)
- CHF currently costs the US healthcare system
   S \$31B in hospitalisation costs alone
- SOZO® can detect small changes in fluid levels that typically pre-empt a major cardiac event which may be avoided by adjusting medication

Addressable Market >US\$1.0 billion p.a.

# Cancer Survivors

- More than 15 million in the US
- 1 in 3 people will develop lymphoedema
- Cancer survivors have a 15-fold increased risk of developing heart failure



# L-Dex® for the Early Detection of Subclinical Lymphoedema

Lymphoedema is a leading post-surgical complication for many cancer patients and greatly impacts quality of life. Simple and accurate measurement of fluid in limbs allows early detection and intervention.



- Cancer treatment can damage the lymphatic system and result in fluid build-up in the extremities
- It can become an irreversible, life-long, debilitating condition that progressively gets worse



- L-Dex® detects the onset of lymphoedema very early, ~35 ml of fluid build up versus 200 ml+ for other approaches
- SOZO® with L-Dex® is designed to be used both clinically and by patients at-home



 If detected early, the progression of lymphoedema can be prevented, and often reversed

# **Drivers for Growth Continue to Expand**

SOZO®'s predecessor BIS device, the U400, has provided the commercial proof-of-principle, clinical data, and validation of the clinical benefit of monitoring cancer survivors with L-Dex®

#### Clearances in place

- Jun 2013 unencumbered 510(k) clearance for L-Dex®
- Aug 2017 SOZO® cleared for assessment of unilateral lymphoedema in the US
- Apr 2018 SOZO® cleared for assessment of bilateral lymphoedema in the US

- Reimbursement in place Jan 2015 dedicated Category I CPT® Code for L-Dex® came into effect at US\$112/test
  - July 2018 Proposed increase to CPT® I Code announced (to US\$146/test effective Jan 2019)
  - Currently aiming to extend coverage to include private payors

#### **Guidelines in place**

- NCCN requires breast cancer patients monitored for lymphoedema
- ASCO & ACS issue joint guidelines on managing lymphoedema
- APTA guidelines for using L-Dex® to monitor breast cancer patients
- NLN & NAPBC survivorship guidelines with focus on lymphoedema

# Independent Clinical Evidence Continues to Expand

Multiple, independent, investigator-led clinical studies have reported significantly lower rates of clinical grade lymphoedema by monitoring patients with L-Dex® and intervening



Investigator	Duration	Reported Outcomes	Percent Improvement	Number of Patients
*Kilgore 2018	2014-2017	<ul> <li>34% identified elevated L-Dex® followed by intervention</li> <li>6% progressed to clinical stage disease versus reported incidence rate of 20-40%</li> </ul>	82%	146
Whitworth 2017	2010 - 2016	<ul> <li>12% identified elevated L-Dex® followed by intervention</li> <li>3% progressed to clinical stage disease versus reported incidence rate of 10-50%</li> </ul>	75%	596
Kaufman 2017	2010 - 2016	<ul> <li>10% identified elevated L-Dex® followed by intervention</li> <li>0% progressed to clinical stage disease versus reported incidence rate of 20-53%</li> </ul>	100%	206
Laidley & Anglin 2016	2008 – 2013	<ul> <li>12% identified elevated L-Dex® followed by intervention</li> <li>3% progressed to clinical stage disease versus reported incidence rate of 3.5-47%</li> </ul>	75%	326
Soran 2014	2010 – 2013	<ul> <li>33% identified elevated L-Dex® followed by intervention</li> <li>4% progressed to clinical stage disease versus reported incidence rate of 36%</li> </ul>	88%	186
Total Patients Evaluated				1,460

\*Kilgore Study Conclusion: "Our results demonstrated that early conservative intervention for breast cancer patients high risk for BCRL who were prospectively monitored by utilizing BIS significantly lowers rates of BCRL. These findings support early prospective screening and intervention for BCRL. Early detection with patient-directed interventions improves patient outcomes and decreases the risk of persistent BCRL."

# PREVENT Trial — Pre-specified Interim Analysis

#### **Trial Design**

- Multi-centre, prospective, randomised controlled trial
  - 1,100 patients enrolled
  - Followed for 3 years
- 10 medical centres across the US and Australia
  - Majority NCI designated cancer centres
- To achieve a <u>relative</u> 20% improvement over the standard of care — a tape measure

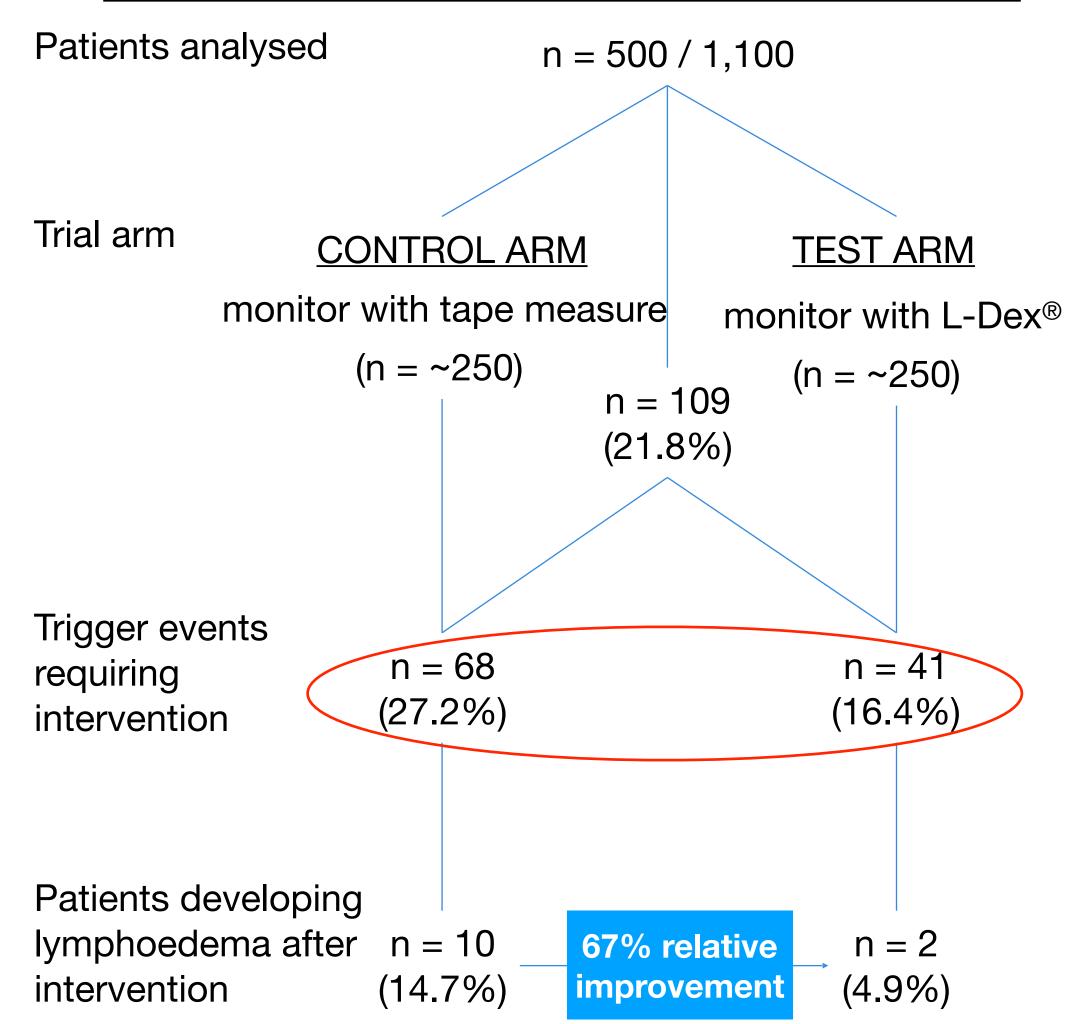
#### **Primary Aim**

 To determine if subclinical detection of extracellular fluid accumulation via BIS and subsequent early intervention reduce the rate of progression relative to rates seen using standard tape measurements

#### **Interim data**

- Early results demonstrate a 67% relative improvement in progression to clinical grade lymphoedema in the L-Dex arm compared to tape measure arm
- Reflecting what others are seeing in their clinical practice

#### 12 Month Interim Data from PREVENT Trial



# Successfully Transitioning to High Margin, High Growth, Subscription Business Model

#### Pre SOZO®

- Had over 120+ hospitals and clinics using L-Dex®
- Previously a capital equipment/disposable business model
- These customers testing only small sub-set of patients due to reimbursement and operational issues

#### **Initial SOZO® Introduction Results**

- Actively converting current and adding new targeted customers to SOZO® Platform and subscription model
- Hospital and clinic customers signing multi-year contracts
  - Converted hospitals and customers testing greater number of patients
  - Substantial increase in revenue in converted hospitals and clinics
  - Substantial increase in number of devices ordered in converted hospitals
- Have converted more than 15% of existing hospital and clinic customers
- Aiming to convert the majority of all existing customers in next 12 months
- Expanded clinical utility of SOZO® in the current guidelines, and recent clinical studies are all drivers of increased usage by existing customers and on-boarding of new customers
- Ability to continue to increase contract value for each customer over time by addition of incremental SOZO® indications and modules

## Centre of Excellence - Example

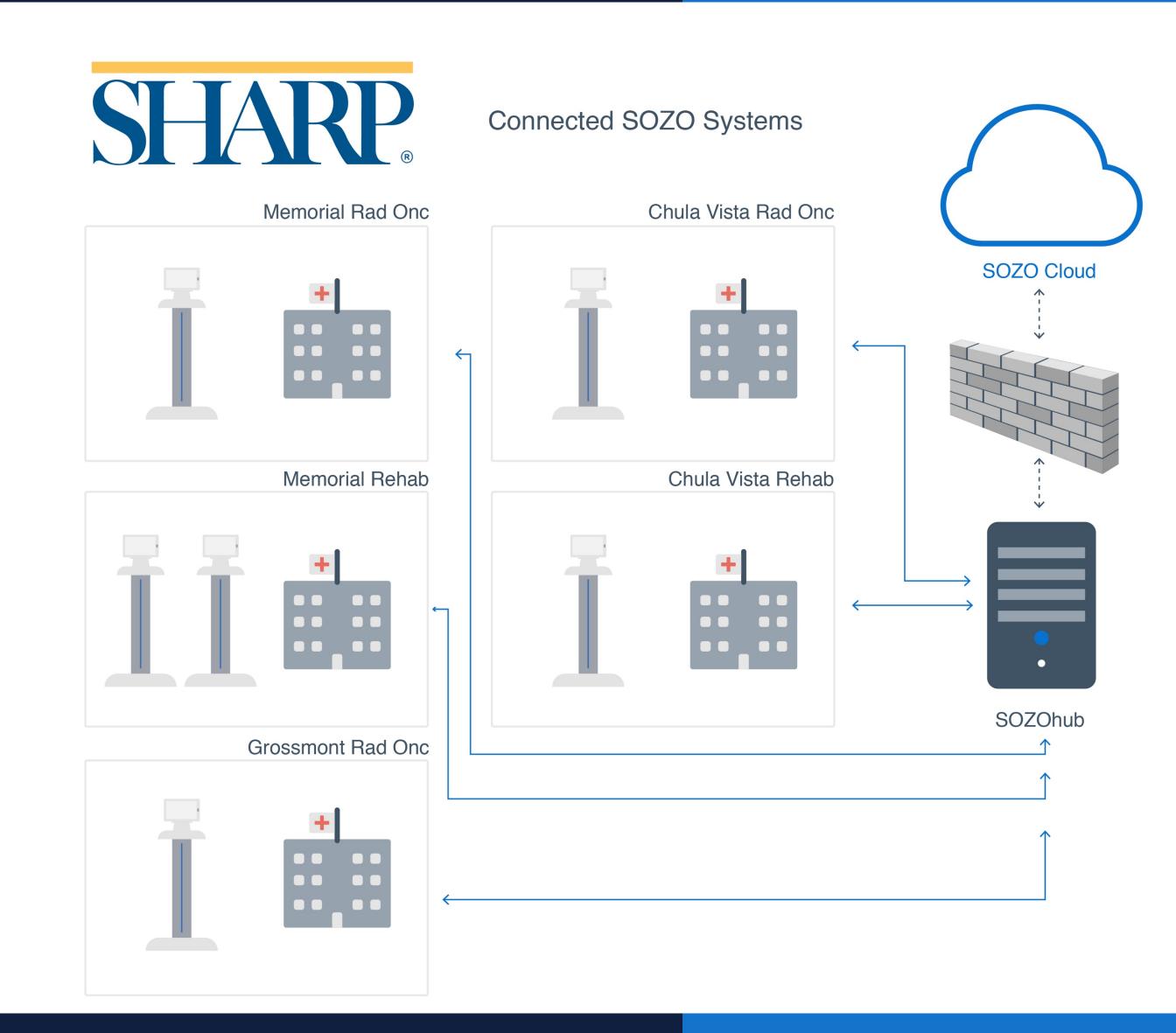
#### **Evolution and Acceleration of SOZO®**

- 6 SOZO® Digital Health Platforms installed across 3 hospitals
- Adding 9 SOZO® Digital Health Platforms in the coming months
- Developing reporting and protocol adoption metrics
- Have agreed to integrate data into EHRs with physician notifications (flags)
- Have expanded testing beyond lymphoedema,
   >25% of all patient assessments are for tissue analysis

#### **Two New Centres of Excellence including**



- NCCN Founding member
- Principal Investigator for PREVENT Trial
- Kilgore paper



# Chronic Heart Failure

- Global pandemic affecting at least 26 million people worldwide
- 1 in 5 people over the age of 40 will develop heart failure
- Most common cause of hospitalisation of people aged over 65 years
- Overall global economic cost in 2012 was estimated at \$108 billion per annum



#### **CHF Overview**

CHF is a chronic, progressive and debilitating condition

#### Among the most expensive diseases for the US Healthcare system

6.5M+
patients

US\$31B+
hospitalisation costs alone

Reducing hospital stay and readmission is a major focus

US government funding bonuses and assessing penalties for physicians and hospitals that over/under perform

#### Assessing / monitoring fluid status is critical to the management of CHF patients

A change of fluid status may signal the need to increase/ decrease medication levels

Correct medication levels significantly reduce hospital stays and readmissions

## Role of SOZO® in Optimising Outcomes for CHF Patient Management

- Current practice is to monitor CHF patients daily for fluid burden in clinic and at-home
- Current monitoring methods have major shortcomings

Weight Scale	•	Inaccurate and rudimentary (although low cost ~US\$150 per month)
Implantable's	•	Invasive and expensive ~US\$25,000 (although accurate/precise)

SOZO® is uniquely positioned to replace current monitoring methods



Precision/accuracy of implantable...



...at the cost of a scale

#### **US CHF Business Model**

#### **Initial focus on Class III CHF Patients**

- Estimated at 25% of US 6.5 million CHF patients
- Monitor and manage the disease progression for Class III patients

#### **SOZO® CHF Usage Model**

- Baseline reading to be performed in a clinical setting
- Daily monitoring to continue in either a clinical or remote setting

#### **SOZO® CHF Revenue Model**

- Initial device purchase plus a per patient per month subscription model
- Well established and growing in CHF market

Preliminary Estimate of Initial US A	ddressable Market
Estimated initial patient population	~1.6 million
Preliminary estimated addressable per annum US market based on US\$60 per patient per month over 12 months	>US\$1.0 billion <sup>1</sup>

1. Excludes revenue from initial device sales

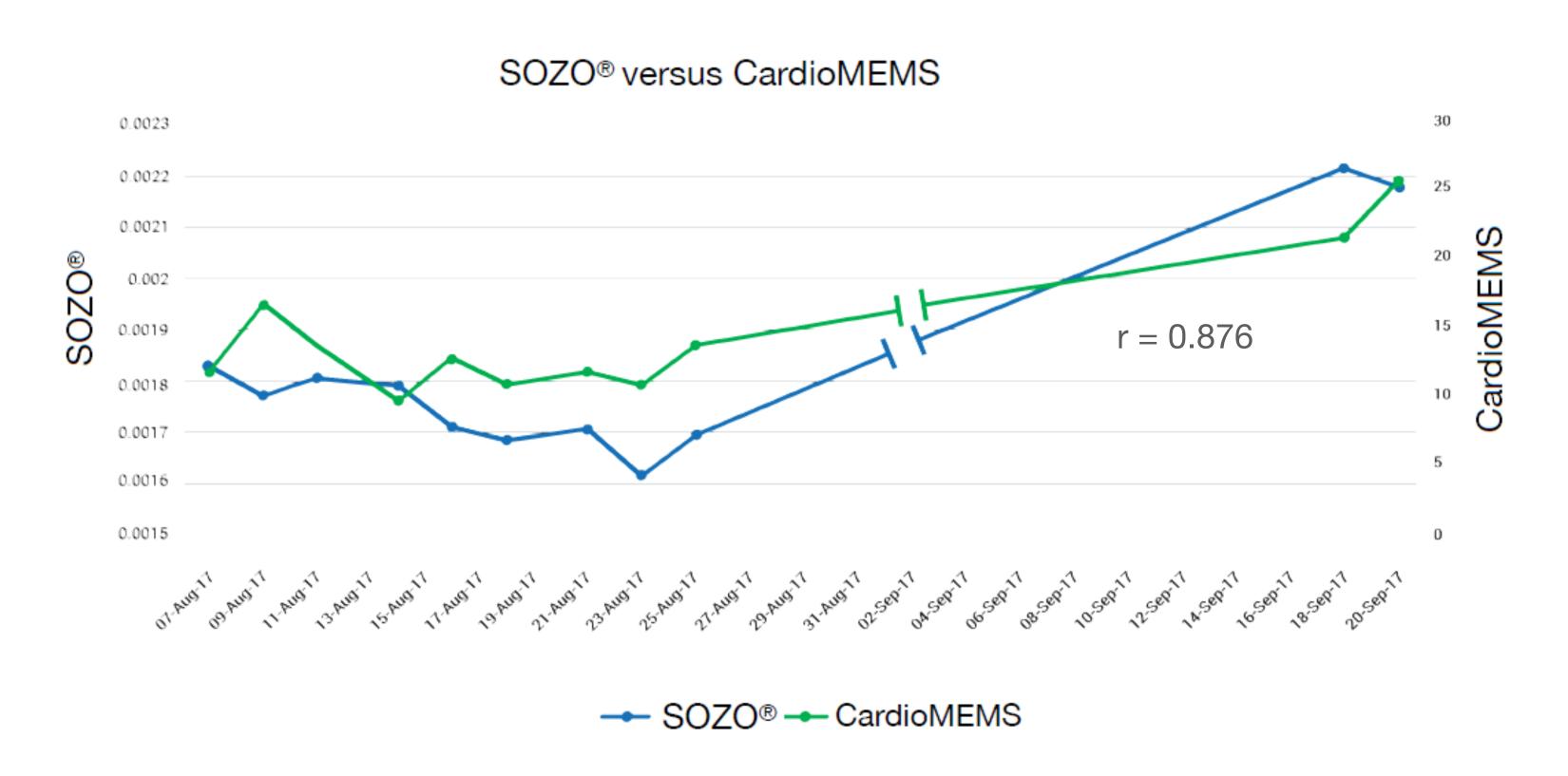
# Strong Correlation Between SOZO® and CardioMEMS

#### **Case Study**

- Patient with advanced heart failure, implanted CardioMEMS device, multiple comorbidities
- Changes made in diuretic medication to keep fluid balance stable
- Weight, mental acuity, as well as PA pressures were utilised to guide therapy
- During the monitoring period patient experienced periods of dehydration and subsequent fluid overload

#### **Conclusion**

SOZO BIS measurements had a correlation coefficient of 0.876 with changes in diastolic pulmonary artery pressure as measured with CardioMEMS to detect fluid excess and impending congestion before hospitalisation



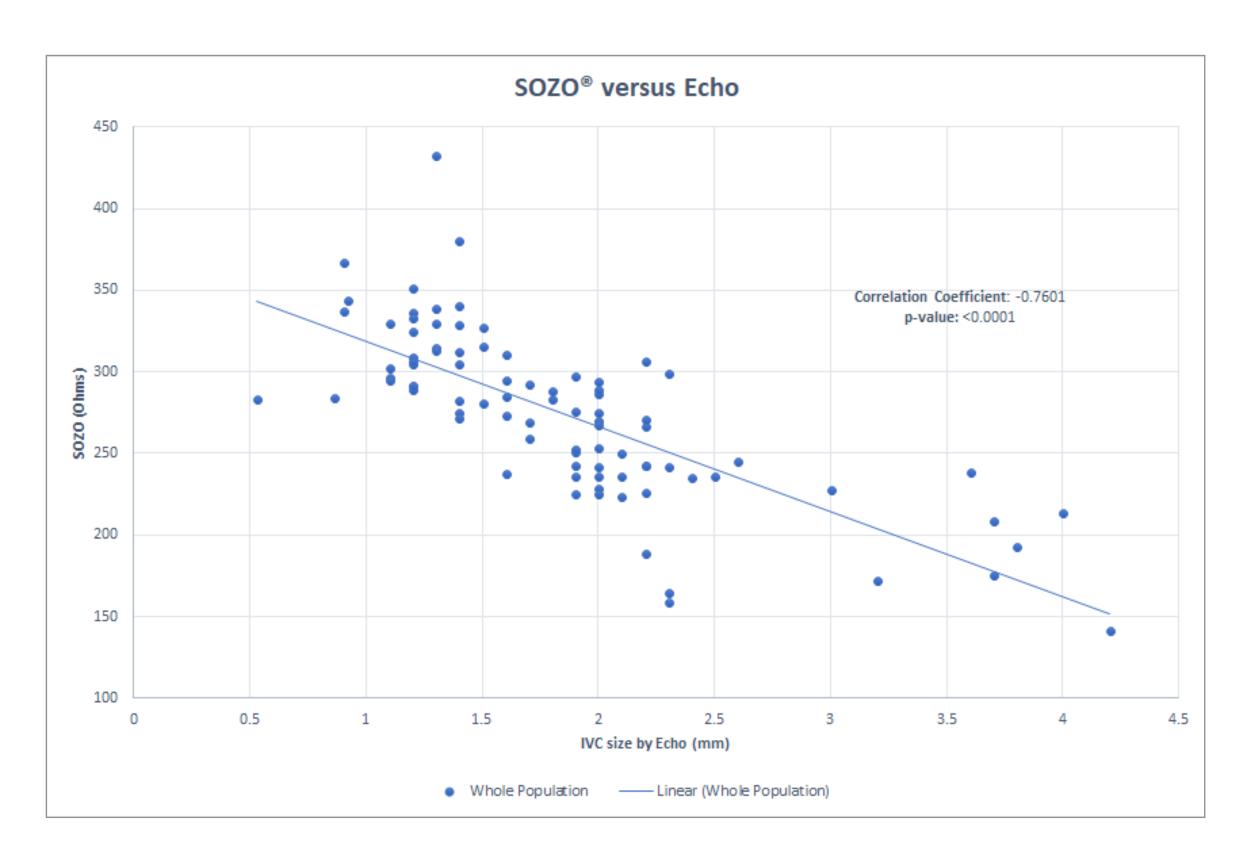
# Clinical Utility of SOZO® to Monitor Patients with Congestive Heart Failure

#### **Background**

- Bioimpedance has been used to track fluid changes in the human body for many decades
- ImpediMed technology demonstrated to be sensitive to volume changes associated with heart failure in multiple publications
- Echocardiograph routinely used to assess heart failure status
- Inferior Vena Cava (IVC) size as determined by an echocardiograph correlates to reduced hospital readmission

#### **EARLY SOZO® RESULTS**

- NYHA Class II/III patients followed 3 times a week over 4 week period
- Measures: SOZO®, echocardiograph to measure Inferior Vena Cava size, weight, signs and symptoms
- Strong correlation demonstrated between SOZO® and echocardiographic parameters



#### **Heart Failure Action Plan**

#### **SOZO®** Regulatory Milestones

- CE Mark achieved June 2017
- FDA 510(k) clearance for fluid monitoring for CHF achieved December 2017

#### **Clinical Data for Marketing Purposes**

- Working with world leading institutions on CHF trials
  - First data to be presented at World Congress on Heart Disease July 2018
  - Second study submitted for editorial review
  - Several other papers being drafted
- Data from initial CHF studies has led to initiation of larger multi-centre study
  - Study initiated
  - ~200 patients
  - Fluid measurements during hospitalisation for CHF and daily for 45 days after discharge (at-home)
  - Study will be catalyst for initiating broad market release

#### Favourable Reimbursement and Guidelines Regime

- Reimbursement code established to pay providers to remotely manage patients
- Current guidelines in place for daily monitoring of Class III patients for fluid burden in US

# **Expected Upcoming News Flow**

#### **SOZO®** and L-Dex®

- PREVENT Trial publications
- PREVENT educational seminars commence nationally in August
- New Independent Abstracts and Presentations of further clinical data supporting L-Dex®
- Private payors begin coverage of L-Dex® catalyst for broad adoption in US
- Continued strong growth in SOZO® subscription based business

#### **SOZO®** for Heart Failure

- Release of additional CHF studies utilising SOZO®
- Completion and results of larger multi-centre marketing study
- Commercial expansion of CHF

July 2018

26

# Appendix



# **Management Team**

#### Deep and Broad Commercialisation Experience



Richard Carreon

Managing Director and
Chief Executive Officer

- Joined July 2012
- 30+ years experience
- Extensive experience in the medical device field and growth companies
- Previously VicePresident at Medtronic(10 years)



Frank Vicini, MD
Chief Medical Officer

- Joined September 2014
- 25+ years as radiation oncologist
- Completed his fellowship at Harvard Medical School, has authored over 200 peer reviewed publications, and participated in 6 NIH clinical trials and the MammoSite Registry trial



Morten Vigeland
Chief Financial Officer

- Joined April 2011
- 20+ years in financial management in the medical technology industry
- Experience in med-tech start-ups and emerging growth companies



Catherine Kingsford SVP Medical Affairs

- Joined January 2007
- 20+ years global clinical experience with medical devices
- Previously worked as a cardiac scientist at several world-class medical institutions including St. Andrew's War Memorial Hospital, The Prince Charles Hospital, and Royal Brompton Hospital



David Adams
SVP Ventures, Licensing &
Corporate Development

- On Board November 2013 to August 2016
- Joined August 2016
- Background as medical device investment & business development executive
- 25+ years experience in tax, financial planning, and business development
- Previously Vice President, Integrations and Divestitures at Medtronic



Dennis Schlaht SVP Quality, R&D and Technology

- Joined October 2007
- 30+ years in engineering development and product marketing
- Previously Vice
  President of Marketing
  and Product
  Development at
  XiTRON's Test and
  Measurement Business



Nancy Deisinger
VP Human Resources

- Joined July 2016
- 20+ years in human resources, including 10+ years in medical device, working with start-ups to Fortune 500 companies
- Previously AVP Human Resources at 3E Company



Shashi Tripathi
Chief Technology Officer

- Joined July 2018
- 20+ years as a healthcare technology leader
- Previously SVP of Technology & Operations at New Century Health, where he oversaw all aspects of IT, project and product management, product development and operations

#### **Board of Directors**



Scott R. Ward
MS, BSc
Non-Executive Director

- Joined July 2013
- Venture capitalist with 30+ years experience in healthcare industry
- Previously Senior Vice President and President of the Cardiovascular business of Medtronic
- Chairman of the Board of Creganna-Tactx Medical Devices and Cardiovascular Systems, Inc.



Gary Goetzke
Juris Doctorate
Non-Executive Director

- Joined August 2016
- 15+ years in senior management positions with medical device companies
- Currently the Principle and Chief Executive Officer of Compass Medical Advisors, LLC



Robert M. Graham AO, FAA, FAHMS, MBBS, MD, FRACP, FACP, FAHA Non-Executive Director

- Joined January 2018
- Received medical training at the University of South Wales where he is now the Des Renford Professor of Medicine
- Inaugural Executive Director, Victor Chang Cardiac Research Institute, Sydney Australia
- 17+ years experience in US healthcare and currently a consultant physician in cardiovascular diseases



Richard Carreon

Managing Director and
Chief Executive Officer

- Joined July 2012
- 30+ years experience
- Extensive experience in the medical device field and growth companies
- Previously Vice
   President at Medtronic
   (10 years)



Judith Downes
Non-Executive Director

- Joined April 2017
- 20+ years of accounting and senior management expertise with large ASX listed companies
- Previously a CFO at Alumina Limited and CFO/ COO of Institutional Division, ANZ Banking Group Limited
- Currently Board Chairman of Bank Australia Limited and Honorary Fellow of the University of Melbourne's Faculty of business and Economics



Donald A. Williams
BAcy, CPA
Non-Executive Director

- Joined March 2017
- 35+ years in leadership roles serving the life science, biotech, and medical device industries
- Currently the Audit
   Committee Chair of Akari
   Therapeutics, Alphatec
   Holdings, Marina Biotech,
   and Proove Biosciences,
   and the Compensation
   Committee for Marina
   Biotech



Amit R. Patel
MBA, BME
Non-Executive Director

- Joined March 2017
- 8+ years in senior management positions
- Currently on the board of Vios Medical and Pillsbury United Communities
- Currently the CEO and Co-Founder of Vios Medical