

# impedimed®

**Investor Presentation**

ASX:IPD October 2018

**Annual General Meeting**





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# Investment Highlights

## Large and Attractive Markets

- Cancer Survivorship >US\$1.8 Billion annually
- Chronic Heart Failure >US\$1.0 Billion annually
- Successfully building high margin SaaS subscription business

## Differentiated Advantages

- Highly disruptive non-invasive digital health platform for the clinical monitoring of fluid and tissue
- Robust patent portfolio with more than 40 families
- Cloud based data of patient measurements allows for proprietary analytics and algorithm optimisation

## Significant Body of Clinical Evidence

- Lymphoedema – PREVENT Trial and 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

## Regulatory Clearances

- FDA Clearance for the clinical assessment of unilateral and bilateral lymphoedema
- FDA Clearance for monitoring patients with CHF (clinical and at-home monitoring)
- CE Mark for multiple indications including lymphoedema, CHF, renal failure

## Reimbursement

- 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)



# Major Achievements Last 12 Months

## Growing Body of Clinical Evidence Strengthens BIS Value Proposition

- Lymphoedema
  - PREVENT Lymphoedema Trial Top-line Results
    - 95% reduction in the progression to clinical grade lymphoedema
    - Bioimpedance spectroscopy (BIS) and L-Dex® suggested as the new standard of care for cancer survivors at risk of developing lymphoedema by Principal Investigator of PREVENT Trial
    - First PREVENT Trial paper published with outstanding initial data. The authors from the PREVENT trial concluded that L-Dex® is very sensitive in the assessment of sub-clinical lymphoedema in patients with a history of breast cancer and recommends an aggressive measurement protocol
  - 3 independent studies published showing significant reductions in progression to clinical grade lymphoedema
  - Multiple presentations of new clinical data on reduction of progression of lymphoedema presented at global medical conferences
- Chronic Heart Failure
  - Correlation case study of SOZO® versus CardioMEMS™ (r=0.876) presented at 23rd World Congress on Heart Disease
  - Correlation case study and clinical utility of SOZO® to monitor CHF patients presented at American Heart Congress - CVD

## Subscription-Based SOZO® Digital Platform Introduced

- Since the launch of SOZO® \$5.9 million of contracted revenue booked
- 4 leading cancer institutions become SOZO® Centres of Excellence (University of Kansas, University Hospitals of Cleveland, Sharp Medical Center, and Macquarie University Hospital)

## Guidelines Enhanced

- American Physical Therapy Association (APTA) recommends L-Dex® testing for sub-clinical lymphoedema, expanding the use from current to existing cancer survivors (an 8 fold increase in potential patients)

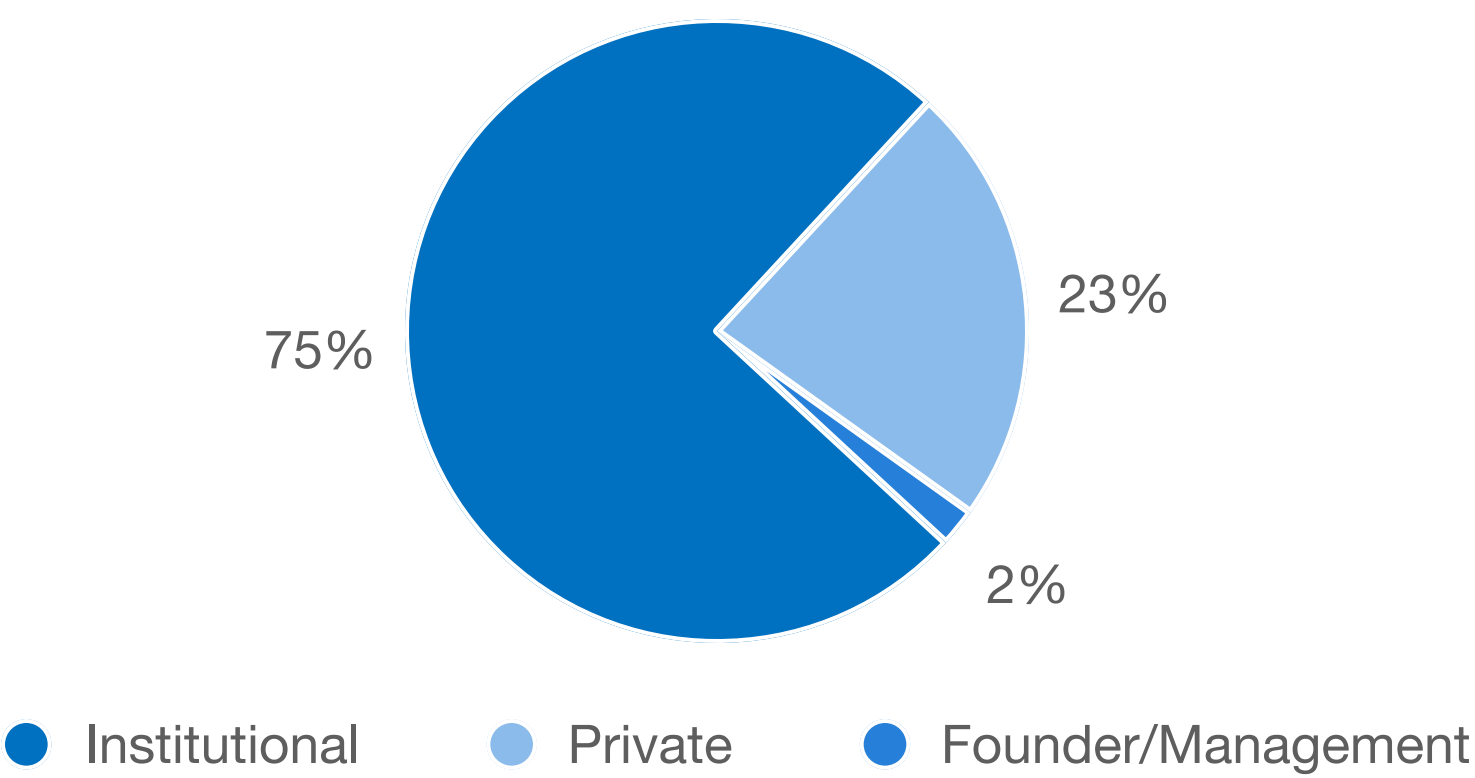
## New and Expanded Regulatory Clearances

- FDA 510(k) clearance received for monitoring fluid in patients with chronic heart failure
- FDA 510(k) clearance received for the clinical assessment of patients with bilateral lymphoedema (expands the potential patient population by more than 700,000 in the US annually)

# Corporate Overview

- ASX listed (October 2007)
- Operations in US (San Diego, CA), Australia (Brisbane) and Europe (Greece) (70 total staff)
- Market capitalisation ~AU\$165M (~379M shares on issue)
- Cash on hand AU\$27.2M (30 September 2018)

## Share Register Breakdown



## Substantial Shareholders

Allan Gray	17.0%
Fidelity (FIL)	7.5%
Starfish Ventures	6.8%
Kinetic Investment Partners	6.4%
Macquarie Group Limited	6.2%
Paradice Investment Management	6.1%



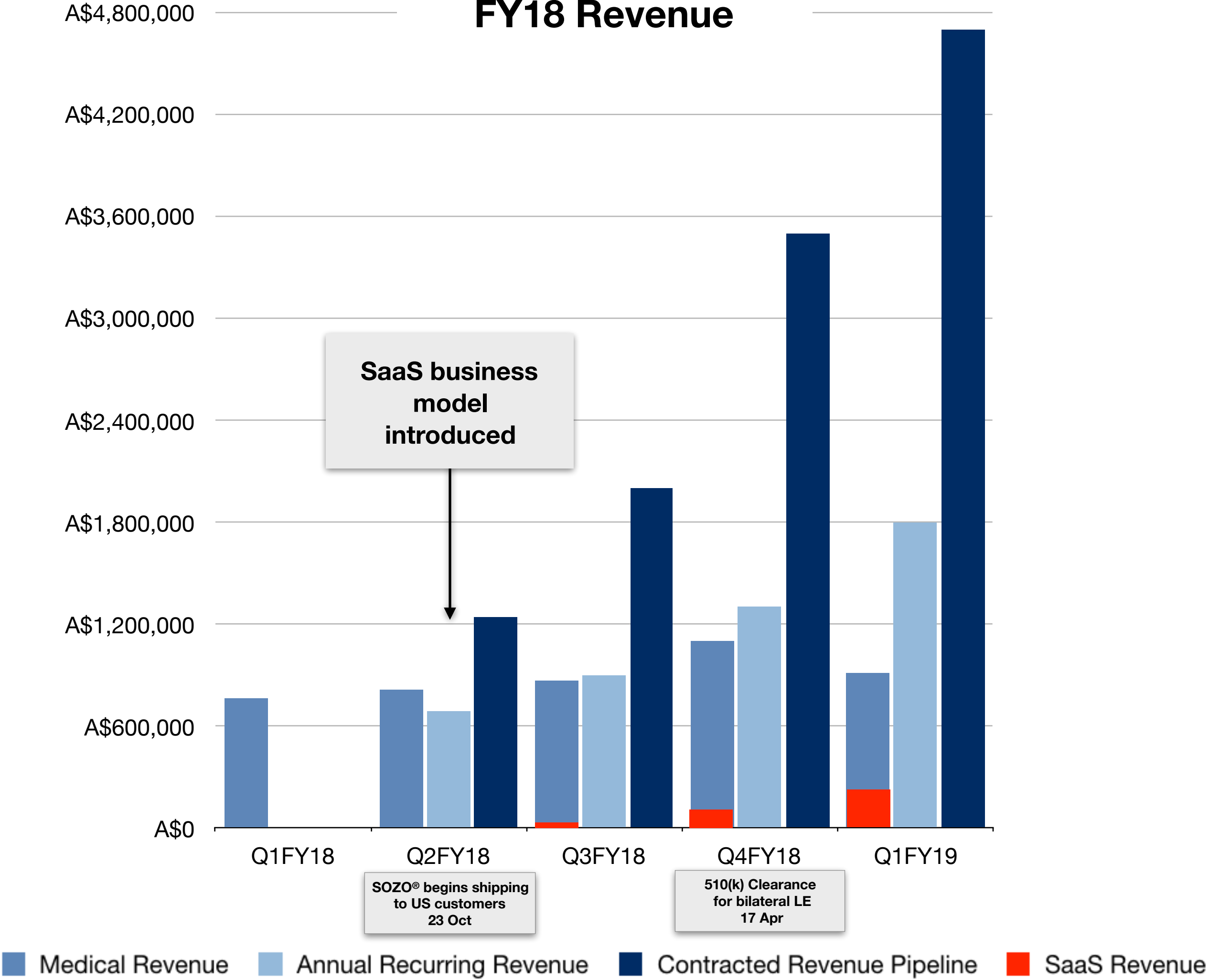
Business Highlights

Key Stats (AUD \$ Millions) (Preliminary and unaudited)	Q4 FY18	Q1 FY19	Change	% Change
Contracted Revenue Pipeline (CRP)	\$3.5	\$4.7	\$1.2	34%
Total Contract Value (TCV)	\$1.9	\$1.4	(\$0.5)	(26%)
Annual Recurring Revenue (ARR)	\$1.3	\$1.8	\$0.5	38%
Medical Revenue	\$1.1	\$0.9	(\$0.2)	(18%)
SaaS Revenue	\$0.1	\$0.2	\$0.1	100%

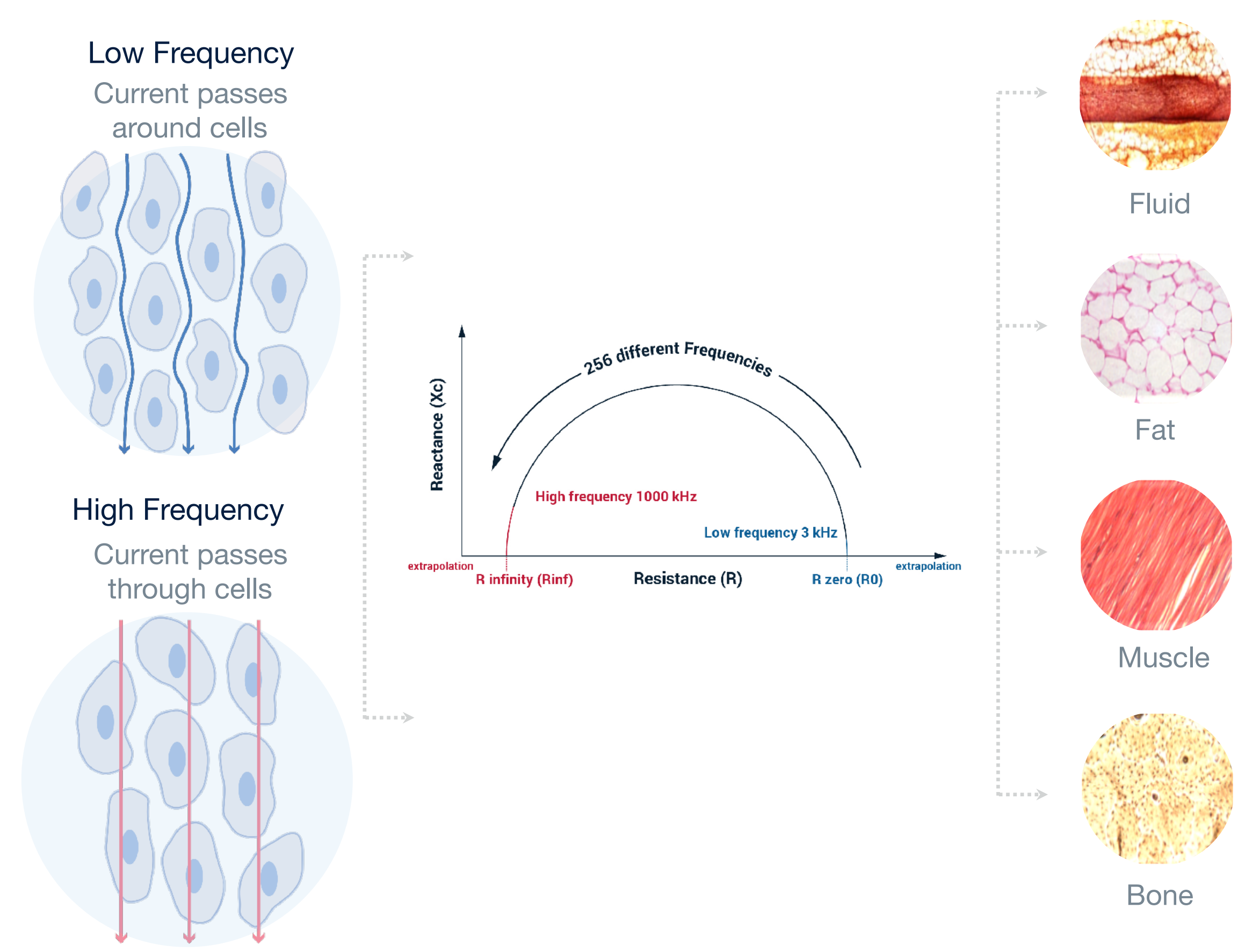
Key Points

- 1. Q2 FY18 began transitioning business to SaaS subscription business model in conjunction with the introduction of the SOZO® Digital Health Platform
- 2. Contracted Revenue Pipeline (CRP) is the future period revenue amounts related to Total Contract Value (TCV) that are yet to be reported as recognised revenue
- 3. Total Contract Value is the total value of customer contracts signed during the period including one-time and recurring revenue
- 4. 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
- 5. Subscription revenue now accounts for 24% of the company’s quarterly medical revenue (up from 10% in the previous quarter)
- 6. Strong customer and SaaS pipeline building

SaaS Business Model  
FY18 Revenue



# BIS Technology is Non-invasive, and provides Fast, Accurate and Medically Meaningful Information



## Advantages

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

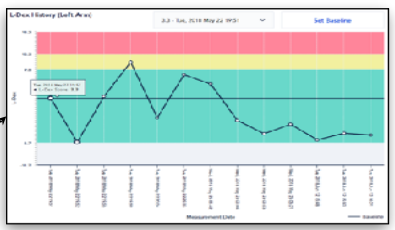


~60% of the human body is made up of water



# SOZO® - Next Generation BIS Digital Health Platform

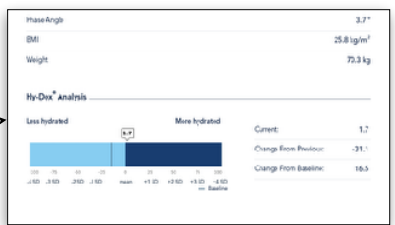
- SOZO® has the potential to change health care by identifying early onset of disease states both in the clinic and at home, leading to improved patient outcomes
- SOZO® is the world's ONLY cloud-based, non-invasive, individualised fluid monitoring device with proven, peer-reviewed accuracy for delivering medically meaningful results in as little as 30 seconds
- SOZO® combines the technology of our world-renowned scientific and medical devices into a single digital health platform
- SOZO® has multiple FDA clearances and CE Mark, with more clearances on the horizon
- SOZO® is the only fluid measurement device with over 1,100 patients enrolled in a randomised controlled trial
- SOZO® will take advantage of data collected for continuous improvement of care
- SOZO® is poised to enter its first billion dollar plus markets (CHF and LE) with a SaaS model which allows for easy upgrades and entry in to other large markets



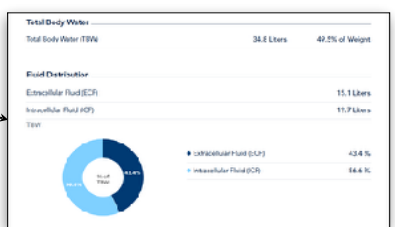
- L-Dex® for assessing sub-clinical unilateral and bilateral lymphoedema



- Chronic Heart Failure fluid monitoring



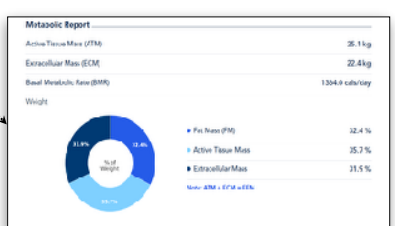
- Hydration status



- Extracellular fluid
- Intracellular fluid
- Total body water



- Fat-free mass
- Skeletal muscle mass



- Protein and mineral content



## Initial Focus on Cancer Survivorship and Chronic Heart Failure

### Cancer Survivorship

- Cancer and its treatments have a huge impact on the body that often affect 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 annually**

### 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 >US \$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 annually**



# Cancer Survivors

- More than 15.5 million in the US
- More than 5 million patients suffering from persistent cancer related lymphoedema
- 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, ~36 ml of fluid build up versus 200 ml+ for other approaches
- L-Dex® has been clinically proven to detect sub-clinical lymphoedema up to 10 months before any visible symptoms



- If detected at stage 0 or stage 1, the progression of lymphoedema can be prevented, and often reversed



# 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 relative 20% improvement over the standard of care — a tape measure

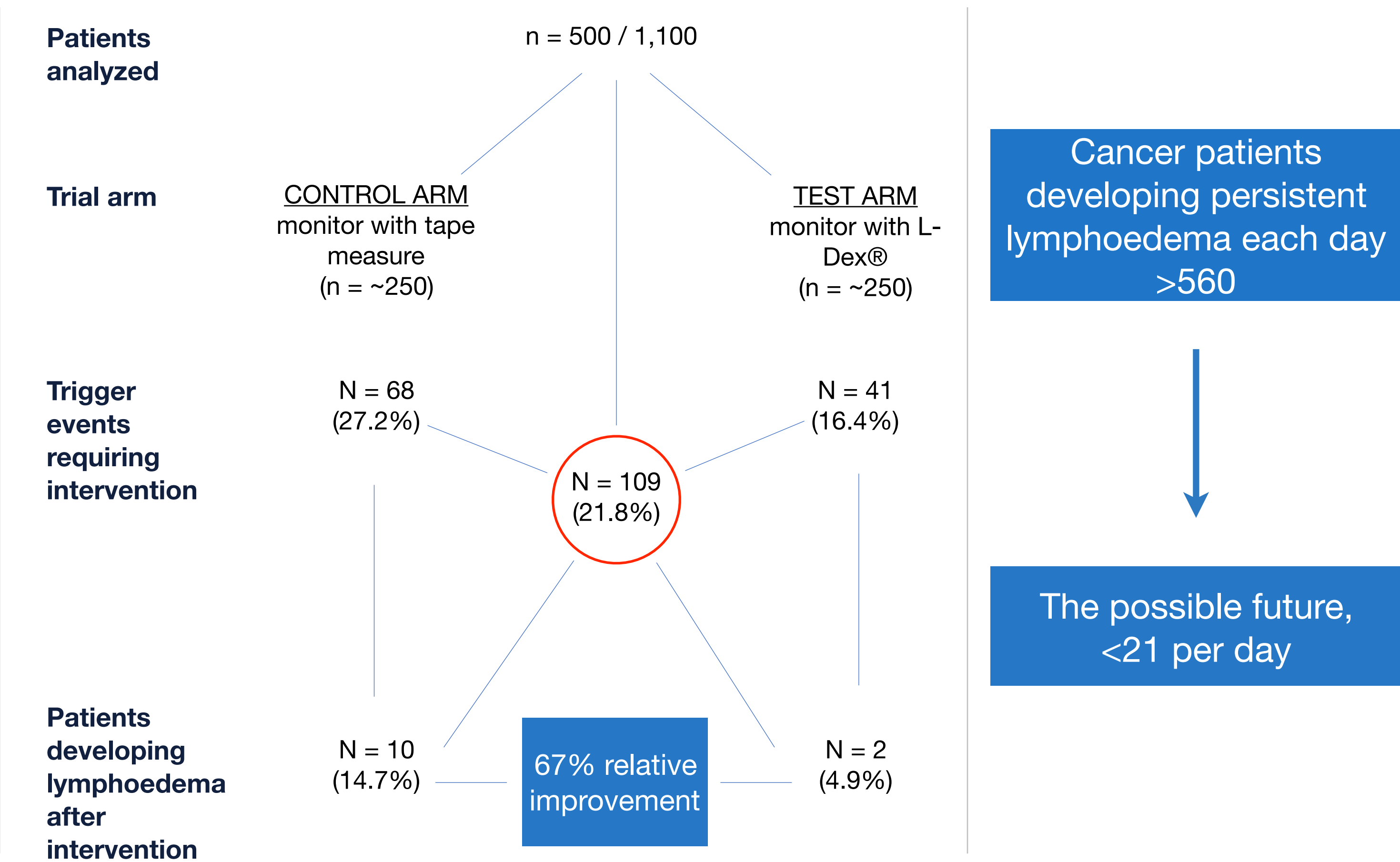
## Primary Aim

- To determine if sub-clinical 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 persistent 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



# Independent Clinical Evidence Continues to Expand

*The North American market for compression therapy is estimated at over US\$1 Billion, a 75% reduction in lymphoedema has the potential to create a favourable impact throughout the medical system*

Investigator	Duration	Reported Outcomes	Percent Reduction	Number of Patients
Kilgore 2018	2014-2017	<ul style="list-style-type: none"><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 style="list-style-type: none"><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 style="list-style-type: none"><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 style="list-style-type: none"><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 style="list-style-type: none"><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

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



# SOZO® Adoption Accelerating

## SOZO® Worldwide Customer Base

- 114 SOZO® customers
  - 71 U400 customers converted
  - 43 new institutions installed
- 234 contracted SOZO® devices
  - Subscription contracts up to 3 years
  - Monthly subscription fee based on indication licensed and estimated initial patient volume
- 12,800 patient assessments completed
  - 72% unilateral lymphoedema
  - 6% bilateral lymphoedema
  - 22% tissue analysis

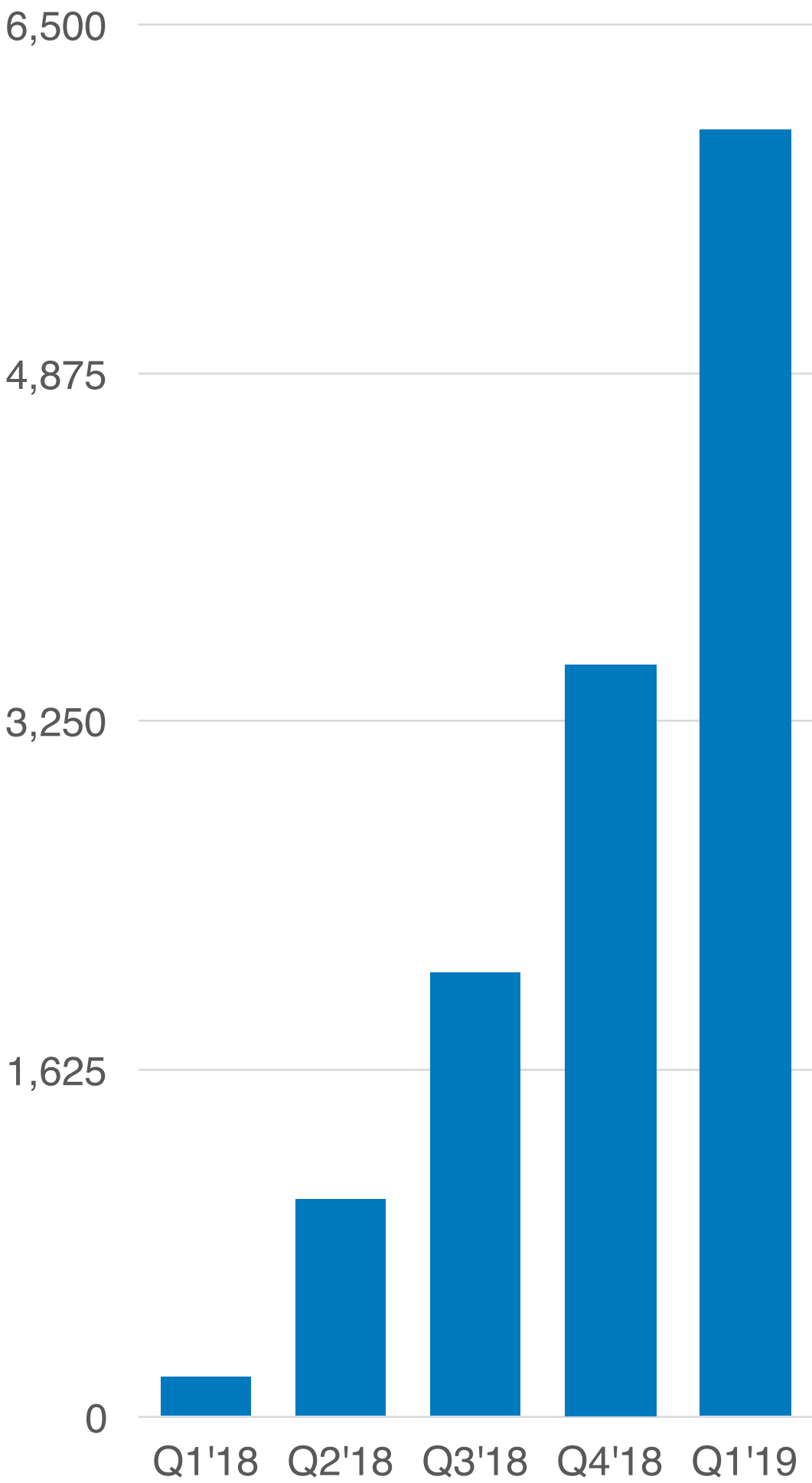
## Impact

- Large cancer institutions contracting for greater number of devices (4:1)
- Expanded testing due to device ease of use and subscription business model
- Increasing patient testing
- Protocol adoption and routine testing taking hold
- Inquiries into new indications
- Inquiries into tissue analysis

## New Revenue Opportunities

- Additional device sales to existing institutions
- Expanded utilisation
- Commercial payors
- New indications and tests

## SOZO® Patient Tests by Quarter



## New Centre of Excellence



### The University of Kansas Cancer Center

- Ranked as one of the nation's leading cancer centres for eight years in a row (US News and World Reports)
- One of only 70 National Cancer Institute (NCI) designated cancer centres
- Accredited by the National Accreditation Program for Breast Centers (NAPBC)
- Commission on Cancer (CoC) accredited

### Evolution and Acceleration of SOZO®

- 5 SOZO® Digital Health Platforms installed at two Breast Surgery Clinics
- 9 additional SOZO® Digital Health Platforms are planned for six medical oncology sites (November 2018)
- Considering adding additional SOZO® units
- Expanding to pelvic cancers in January
- Cancer patients to be tested following a disciplined protocol
- They expect more than 2,000 newly diagnosed cancers patients per year to be enrolled in testing program



## Establishing SOZO® as Standard of Care

### PREVENT Trial Update

- Interim results under peer review
- Submitted to key cancer publication

### SOZO® Reimbursement Strategy

- NCCN Guidelines®
  - Inclusion of formalised protocol and BIS technology
- Commercial Payors
  - Present to key regional payors
  - Request formal technical review
  - Present to top national payors

### Awareness Campaign

- Physicians
  - Presentation of PREVENT data at key medical congresses and physician training meetings
  - Educational seminars expanded
  - Press release of PREVENT Trial results and success stories at key cancer centres
- Institutions
  - Articles in key journals focusing on reducing costs and improving patient outcomes
- Patients
  - Approach key patient advocacy groups to ensure members are aware of the PREVENT Trial interim results and where they can go for testing



# 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 65 years and older
- Overall global economic cost in 2012 was estimated at US\$108 Billion annually





# 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 Devices	• 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 Addressable 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

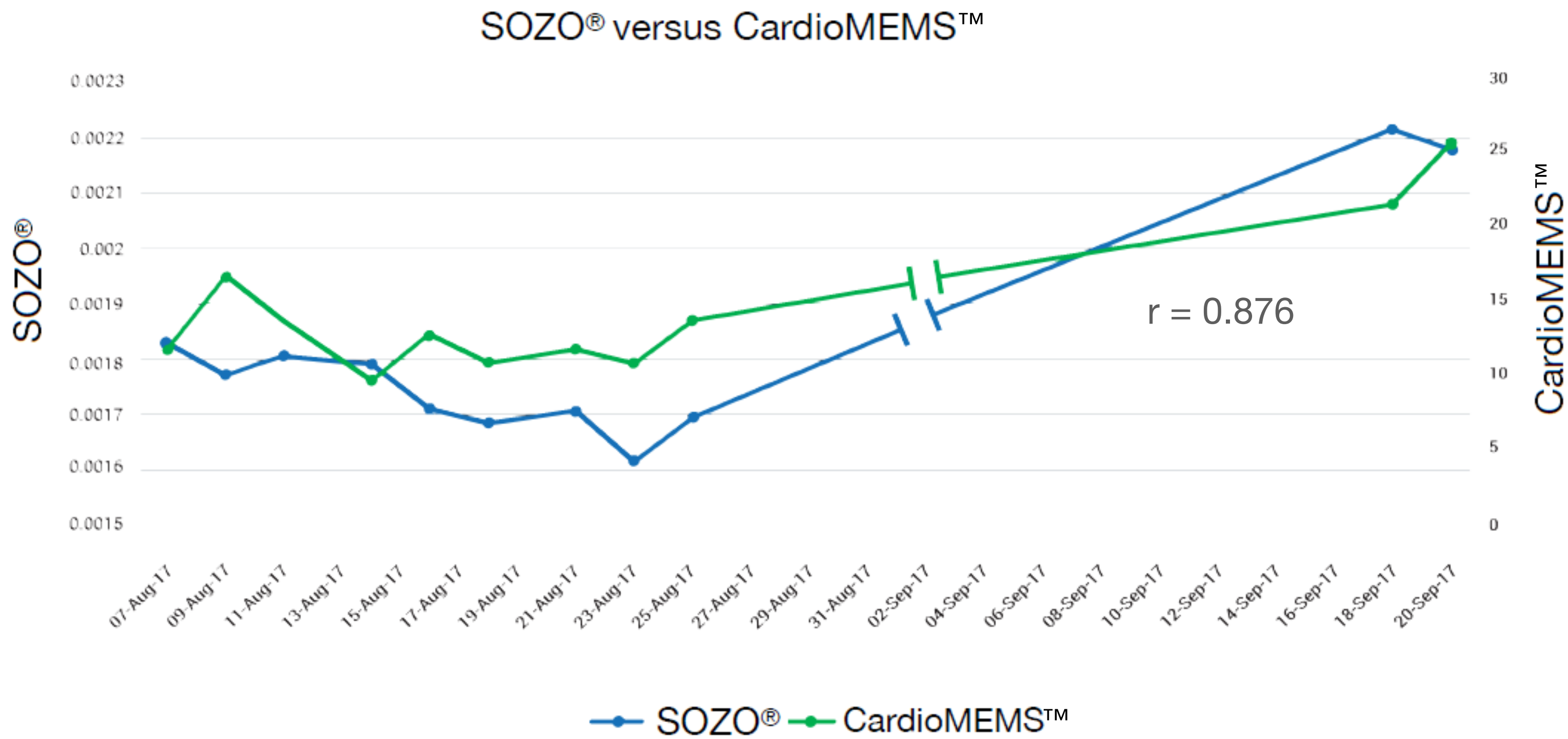
# SOZO® Non-invasively Correlates to CardioMEMS™ at a Fraction of the Cost

## Case Study

- Patient with advanced heart failure, implanted CardioMEMS™ device, multiple co-morbidities
- 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





## Heart Failure Action Plan

### **SOZO® Regulatory Milestones**

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

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

- Working with world leading institutions on CHF trials
  - First data presented at 23rd World Congress on Heart Disease July 2018
  - Correlation case study and clinical utility of SOZO® to monitor CHF patients presented at American Heart Congress - CVD
- Data from initial CHF studies has led to initiation of larger multi-centre study
  - Study commenced, first patient enrolled 9 October 2018
  - ~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

### **Broader Market Release**

- Targeted for 2H CY2019

## Expected Milestones and Upcoming News Flow

### **SOZO® for Cancer**

- PREVENT Trial interim results published
- PREVENT educational seminars expanded
- PREVENT Trial — additional publications
- NCCN Guidelines® — The addition of a formal testing protocol and BIS technology
- Podium presentations at major medical congresses
- Private payors begin coverage of L-Dex® — catalyst for broad adoption in US
- Continued strong growth in SOZO® SaaS subscription based business
- Expanded indications for managing cancer survivors

### **SOZO® for Heart Failure**

- Release of additional CHF studies utilising SOZO®
- Completion and results of larger multi-centre study
- Commercialisation of SOZO® for CHF



# 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 Vice President 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 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