

# chf solutions™

(NASDAQ: CHFS)

Corporate Presentation  
September 2017

17-1015-C



# Forward Looking Statement

*This presentation contains forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of risks and uncertainties. Various factors could cause actual results to differ materially from these statements including our ability to execute on our strategic realignment and to grow our Aquadex business, our post-market clinical data collection activities, benefits of our products to patients, our expectations with respect to product development and commercialization efforts, our ability to increase market and physician acceptance of our products, potentially competitive product offerings, intellectual property protection, our expectations regarding anticipated synergies with and benefits of the Aquadex business, and the other risks set forth under the caption "Risk Factors" and elsewhere in our periodic and other reports filed with the U.S. Securities and Exchange Commission, including our Annual Report or Form 10-K for the fiscal year ended December 31, 2016. We are providing this information as of the date of this presentation and do not undertake to update any forward-looking statements contained in this presentation as a result of new information, future events or otherwise.*

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Aquapheresis and Aquadex FlexFlow are registered trademarks of Sunshine Heart, Inc. now CHF Solutions, Inc.

# Aquadex Business Overview

## Business and Market Overview

- CHF Solutions provides Aquadex and its Aquapheresis therapy, a form of ultrafiltration to reduce fluid overload in heart failure patients, when diuretics fail.
  - Acquired from Baxter in August 2016.
  - FDA 510(k) market cleared and CE marked.
  - Installed base of 500+ consoles, in over 300 US hospitals and successfully used on over 60k patients
- There are over 5 million people in the US with congestive heart failure
- There are approximately 1 million US hospital admissions per year for heart failure
- Approximately 90% of US hospital admissions for heart failure are due to fluid overload

## Product Highlights

- Clinically proven to remove nearly 40% more fluid in patients than conventional diuretic drug therapy over the same period of time
- Patients have 50% lower 90-day readmission rates than those treated solely with diuretics
- Proven in clinical trials to reduce the hospital length of stay for heart failure admissions
- The three largest cardiology societies have published guidelines recommending ultrafiltration



Aquadex Console



Venous Catheter



Blood Circuit Set



# Market Opportunity

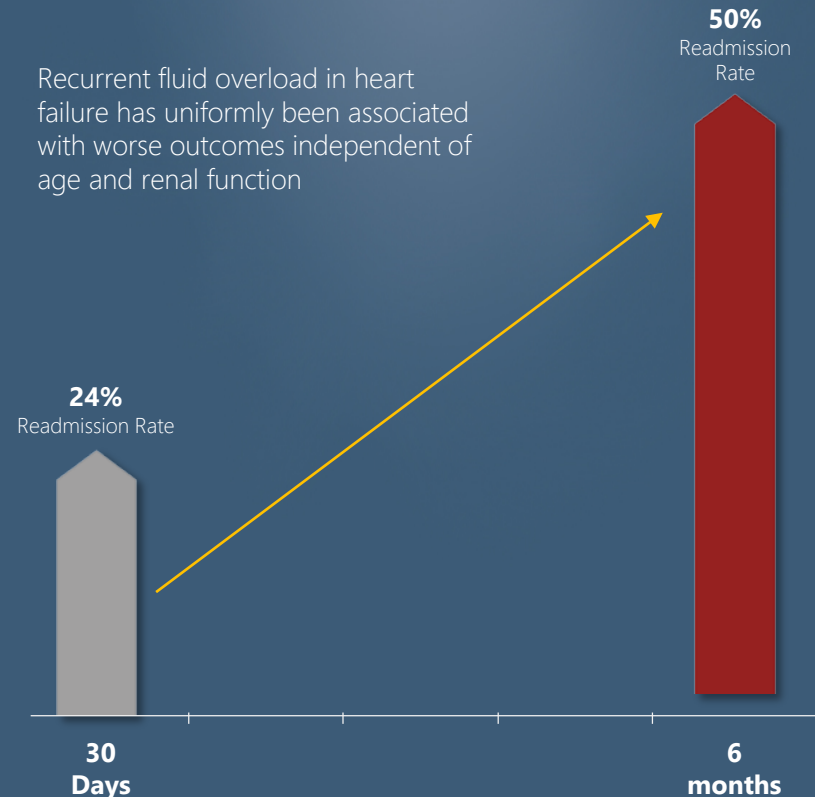
# Heart Failure's Significant Burden

## Congestive Heart Failure

- ~5 million people in the U.S. experience congestive heart failure on an annual basis
- Heart failure is a weakening of the heart's pumping ability, which causes fluid retention in the body
- ~ 1 million hospital admissions per year in US hospitals for congestive heart failure
- ~ 90% of these admissions present with fluid overload
- The average hospital length of stay for a heart failure patient is 6 days, Medicare reimbursement pays a 4 day hospital stay
- Heart failure cost in the US is projected to increase from \$31 billion in 2012 to \$70 billion in 2030

## Challenges of Heart Failure and Fluid Overload

Recurrent fluid overload in heart failure has uniformly been associated with worse outcomes independent of age and renal function



Sources: Ross JS, et al. *Circ Heart Fail*. 2010 Jan; 3(1): 97-103.  
Desai AS, Stevenson LW. *Circulation*. 2012 Jul 24; 126(4): 501-506

# Treatment of Fluid Overload

## Symptoms and Treatment of Fluid Overload

### Symptoms

- Increased weight gain, particularly over short period
- Swelling in legs and arms
- Fluid in abdomen
- Difficulty in breathing and shortness of breath

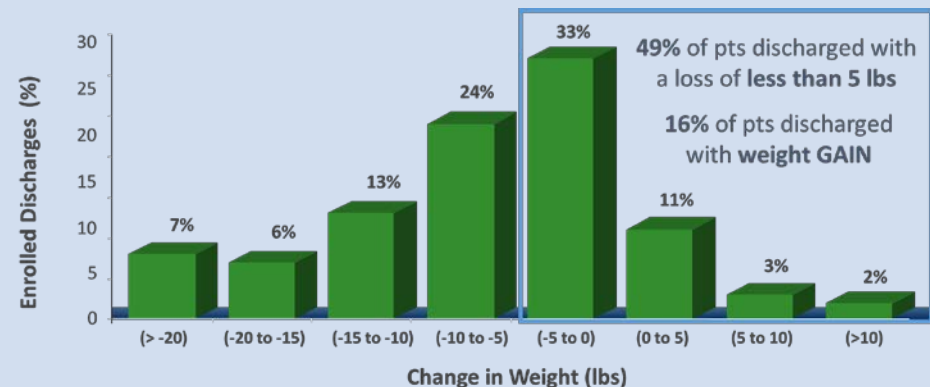
### Treatment

- Diuretic (e.g. Lasix/Furosemide)
- Secondary pharmacologics
- Ultrafiltration

## When Diuretics Fail

**Although effective early in HF, diuretic agents become increasingly ineffective with disease progression**

(due to the development of unresponsiveness in a significant subset of patients).



ADHERE Registry: Weight at Discharge

ADHERE Scientific Advisory Committee. ADHERE Final Cumulative National Benchmark Report. Mountain View, CA: Scios Inc.; 2006



# Today's Healthcare Environment

## Hospital Readmission Reduction Program: Effective as of Oct 1, 2012

- Requires CMS to reduce payments to hospitals with excess readmissions
- Penalty: hospitals can lose  $\leq 3\%$  of Medicare reimbursement

**80% of all Readmissions are due to Heart Failure**

†Readmissions Reduction Program (HRRP). Centers for Medicare & Medicaid Services website.  
<https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.html>. Updated April 18, 2016. Accessed May 25, 2016.





# **Aquadex Product Overview**



# Indications For Use

The Aquadex FlexFlow® System is indicated for:

- Temporary (up to 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy
- Extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization



# Aquadex FlexFlow® System

**Safe • Effective • Predictable**



**Aquadex FlexFlow Console**

- Patented, innovative design
- Easy to use
- Peripheral or central access\*
- Clinician-selected rate of fluid removal (0 – 500 ml/hr)
- Highly automated
- Used often in 4:1 RN ratios in Stepdown

Designed complete with a hematocrit sensor to monitor blood volume changes real time!



**chf** solutions

# Aquadex FlexFlow® System

**Safe • Effective • Predictable**



Aquadex FlexFlow  
Extracorporeal Blood Set

- **Fully integrated blood set**
- **Low blood volume** required, only 35 ml
- Up to 72 hours of inpatient use
- Removes up to 500 ml/hr





## Aquapheresis (Ultrafiltration) Therapy:

- Provides precise control over rate and total volume of fluid removed
- Removes isotonic fluid
  - Extracts more sodium than diuretic therapy while sparing potassium and magnesium<sup>1</sup>
- No Direct Neurohumoral Activation
  - Reset toward a more physiological condition and diuretic efficacy is restored<sup>2</sup>
- Effectively and safely decrease length of stay and readmissions<sup>3</sup>

1. Ali SS, et al. *Congest Heart Fail.* 2009; 15(1):1-4

2. Marenzi G, et al. *J Am Coll Cardiol.* 2001 Oct; 38(4): 963-968.

3. Costanzo MR, et al. *J Am Coll Cardiol.* 2005 Dec 6; 46(11): 2047-2051.

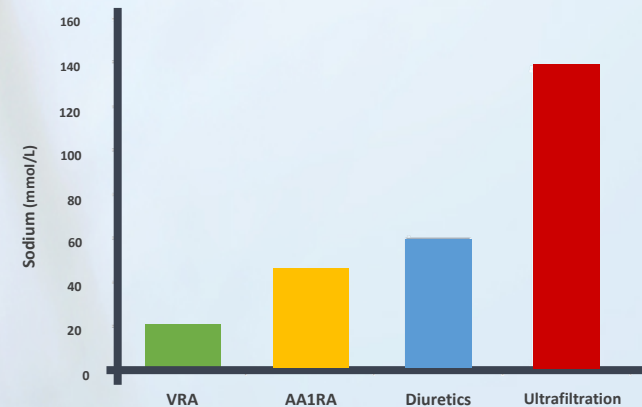




# Aquapheresis

## Removing the Greatest Amount of Sodium

- Aquapheresis has a differential mechanism of action that removes the greatest possible amount of sodium per unit of fluid withdrawn<sup>1</sup>
- No **serum** electrolyte depletion (Mg, K)<sup>2</sup>



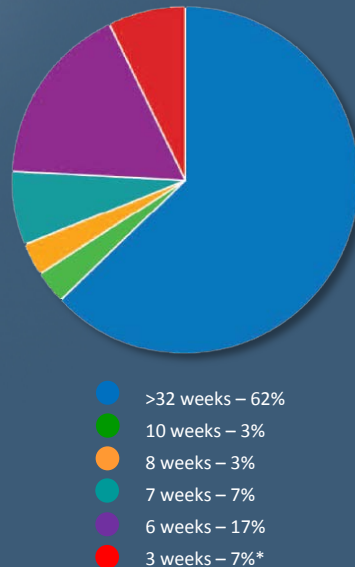
1. Agostoni PG, et al. *Cardiology*. 2001; 96(3-4): 183-189.  
2. Ali SS, et al. *Congest Heart Fail*. 2009; 15(1):1-4

# Good Samaritan Hospital

(A Single Center Experience)

- Independent study on 67 patients who received Aquapheresis
- **No 30-day readmits for volume overload**
- Average of 5.7L removed per patient
- 62% of patients were 32 or greater weeks before next admission
- **Length of Stay when started within 24 hours was 2.2 days**
- Readmission rate from before Aquapheresis down from 12% to 4% the year prior

## Weeks to Admission



Admission unrelated to volume status (n=2)

\*Data presented at the National Teaching Institute & Critical Care Exposition (NTI) in Chicago, IL on May 5-8, 2008. Results may vary.







# Clinical Evidence

# JACC Article (May 16, 2017)

## Significant Clinical Evidence

### Purpose:

#### JACC article reviewed all available clinical data because:

- More than 1 million heart failure hospitalizations occur annually as a result of congestion
- Decongestive pharmacological therapy (diuretics) have not helped

### Conclusions:

- Ultrafiltration is an **attractive alternative** therapy because it **predictably** removes total body sodium.
- The urgency of investigations is underscored by the alarming **prognostic and economic implications** of recurrent **heart failure hospitalizations**, which remain **unacceptably high** with conventional pharmacological therapies.

# Aquadex FlexFlow® Ultrafiltration System

## Significant Clinical Evidence

Study Name	Study Design	# of Patients	Rationale	Publication Date
<b>SAFE</b>	Multi-center, prospective, single-arm	21	IDE for 510k	2003 JCF
<b>RAPID-HF</b>	Multi-center RCT	40 20 UF/20 SC	Early UF vs Diuretics	2005 JACC
<b>EUPHORIA</b>	Single-center, prospective single-arm	19	Early UF in diuretic resistance	2005 JACC
<b>UNLOAD</b>	Multi-center RCT	200 100 UF/100 SC	UF vs SC	2007 JACC
<b>CARRESS-HF</b>	Multi-center RCT	188 94 UF/94 SC	UF vs SC patients with cardiorenal syndrome	2012 NEJM
<b>AVOID-HF</b>	Multi-center RCT	224 110 UF/114 SC (810 planned)	UF vs SC to evaluate readmissions	2015 JACC:HF

# Clinical Guidelines Support Aquapheresis Use

Society	Source
<b>HFSA - Heart Failure Society Of America</b>	HFSA 2010 Comprehensive Heart Failure Practice Guidelines <sup>1</sup>
<b>ESC / HFA - European Society of Cardiology and Heart Failure Association</b>	ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012 <sup>2</sup>
<b>CCS - Canadian Cardiovascular Society</b>	2012 Canadian Cardiovascular Society Heart Failure Management Guidelines Update <sup>3</sup>

**\*CHF Solutions is not recommending the use of Aquapheresis in lieu of diuretics. The Aquadex FlexFlow System is indicated for ultrafiltration treatment of fluid overload in the event of diuretic failure.**

1. Lindenfeld J, et al. *J Card Fail.* 2010 Jun; 16(6): 475 – 539.
2. McMurray JJ, et al. *Eur Heart J.* 2012 Jul; 33(14): 1787 – 1847.
3. McKelvie RS, et al. *Can J Cardiol.* 2013 Feb; 29(2): 168 – 181.

# Aquapheresis Summary

Descriptor	Detail
Indicated for	Patients with fluid overload who have failed diuretic therapy*
Venous Access	Peripheral or central**
Treatment Setting	Outpatient or inpatient (e.g. telemetry/stepdown)
Fluid Removal Rate	0 - 500 ml/hour by 10 ml increments
Blood Flow Rate	20 - 40 ml/min
Blood Set Volume	35 ml
Ease of Use	Only 1 required setting, setup less than 10 minutes

**\*Indication for Use:** The Aquadex FlexFlow® system is indicated for temporary (up to eight hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization. All treatments must be administered by a healthcare provider, under physician prescription, both of whom having received training in extracorporeal therapies.

**\*\*Refer to IFU for warnings related to central venous access.**



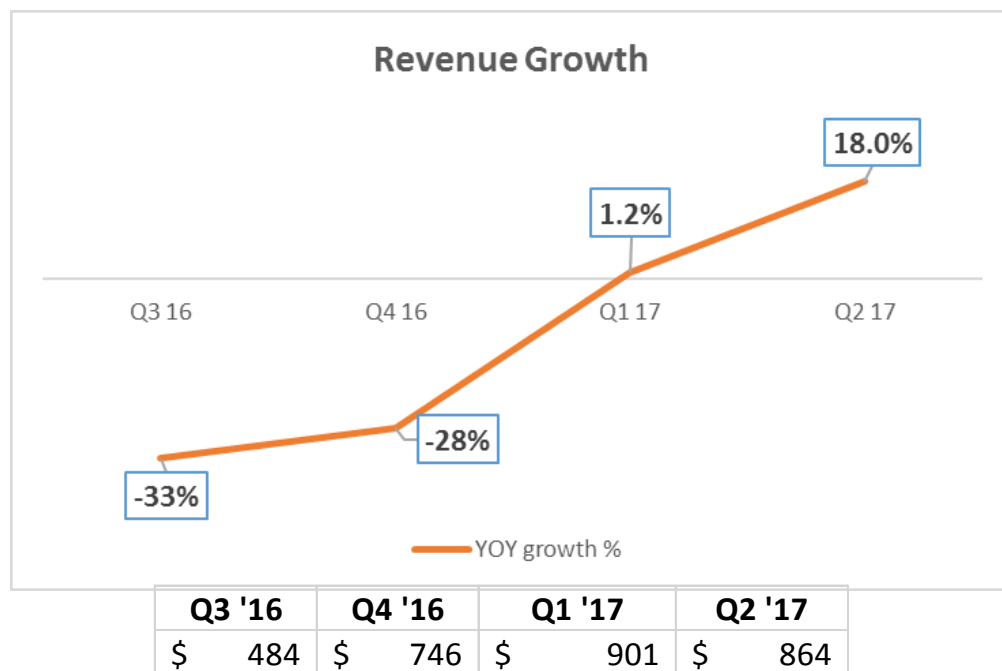


## **Aquadex Revenue Overview**



# Revenue (\$,000)

The acquisition of the Aquadex business in August 2016 coupled with management's new business strategy has delivered increasing revenues and growth



## Q2 2017 update:

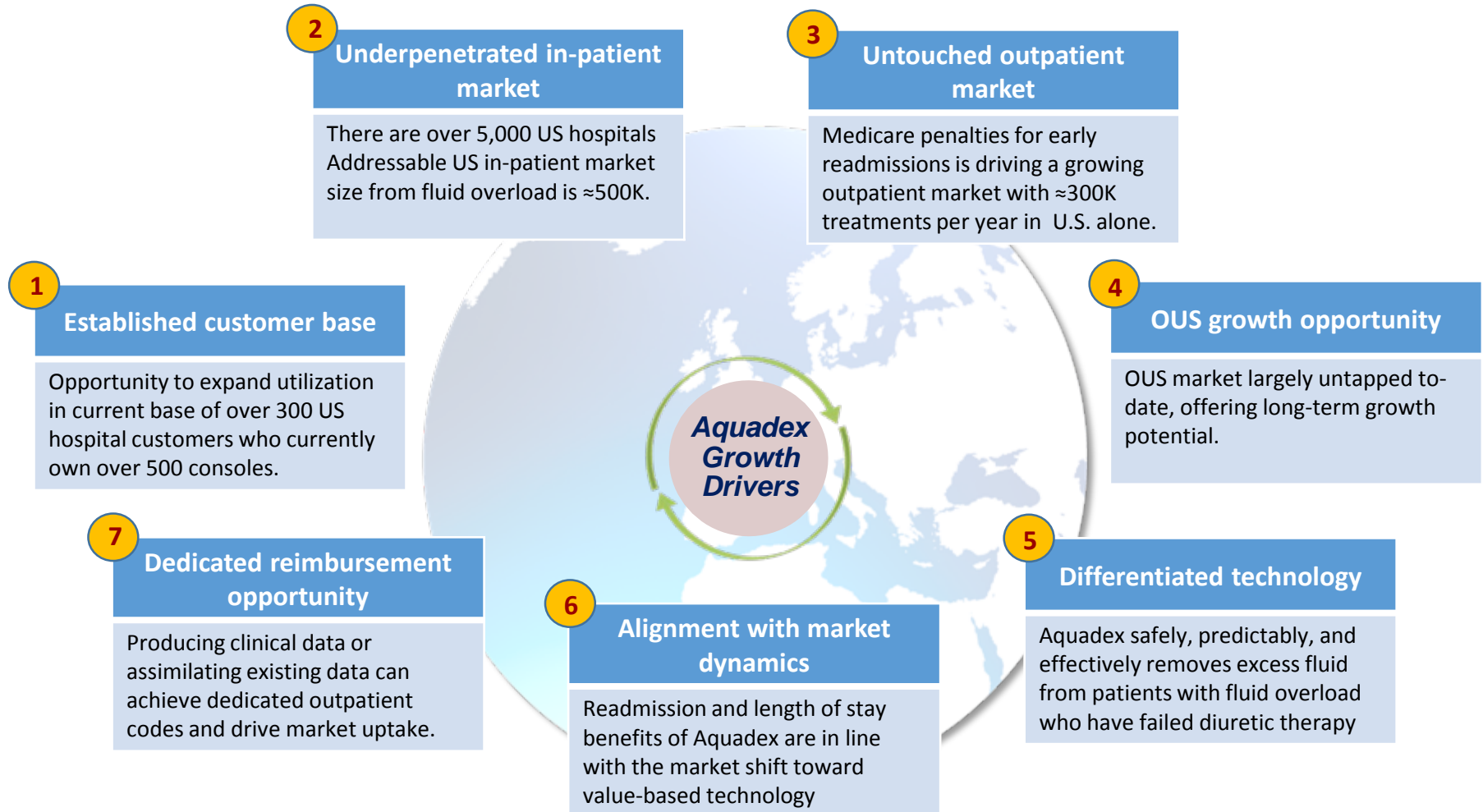
Hired a new Chief Commercial Officer with extensive experience in building commercial organizations

In September 2017, increased our US direct sales force from 4 to 10 sales reps

Focused our strategy on key accounts and account penetration

(\*) Quarterly numbers reflect revenue since August 5, 2016 acquisition

# Growth Opportunities



# Executive Leadership Team



**Megan Brandt**

Senior VP Operations

- 15 Years medical device/pharma experience
- Veteran regulatory & quality professional with provide track record
- B.S. in Biochemistry & Microbiology



**Jim Breidenstein**

Chief Commercial Officer

- 15 years Executive Leadership (President/COO/GM) Experience
- Commercial and Operations Sr Level Leadership
- Paradigm changing technology development - Baxter, Kyphon, Neuronetics, CSI.



**Claudia Napal Drayton**

Chief Financial Officer

- 15 year finance career with Medtronic in United States and Europe
- 20+ years finance/accounting experience
- CPA, MBA Finance and Strategy University of Minnesota



**David Lerner**

Senior VP R&D

- 25+ years of medical device development experience
- Founder of several vascular diagnostic device firms
- Graduate degrees in Medical Physics and Technology Management



**Sandra Eayrs**

VP Human Resources

- 20 years experience in human resources with medical device experience with Boston Scientific and St. Jude Medical
- B.A. degree in Business Administration from the University of Wisconsin



**Gordon Weber**

VP General Counsel

- 19 year legal career, 6 in medical devices, 13 in corporate law
- 12 years finance/accounting experience
- B.A. in Accounting, Valedictorian of William Mitchell College of Law class of 1997

# Board of Directors



**John Erb**

Chief Executive Officer, Chairman

- 40+ years experience in medical devices
- CEO of 4 med-tech start-up companies
- Chairman of 3 public boards
- BA in Business Administration from California State University, Fullerton



**Jon Salvesson**

Non-Executive Member

- Investment Banking and Chairman of the Healthcare Investment Banking Group at Piper Jaffray, focus on the medical device industry
- B.A. in Chemistry from St. Olaf College and an M.M.M. in Finance from the Kellogg Graduate School of Management at Northwestern University



**Warren Watson**

Non-Executive Member

- 35+ years of medical device experience
- 33 years of experience at Medtronic in CRM, HF, Cardiac Ablation, and Cardiology
- Undergraduate and graduate degrees in Engineering from the University of MN



**Greg Waller**

Non-Executive Member

- 40+ years of financial management experience
- Current and past Board member for multiple medical device companies
- 30 years experience as CFO
- MBA in Accounting from California State University at Fullerton



**Matthew Likens**

Non-Executive Member

- President and CEO of Ulthera, Inc. from 2006 to 2016
- President of GMP Wireless Medicine from 2001 to 2006
- Baxter Healthcare Corporation from 1978 to 2001, President of Baxter's Renal U.S.
- B.B.A. in Marketing, Kent State University



**Steve Brandt**

Non-Executive Member

- 35+ years of experience in medical devices.
- VP, Global Sales and Marketing at Thoratec, 2004 to 2015
- VP Sales & Marketing, CHF Solutions 2002 to 2004
- VP of Global Marketing, Cardiovascular Surgery Division for St. Jude Medical, 2000 to 2002
- B.S. from Franklin Pierce College



(NASDAQ: CHFS)

## FOR MORE INFORMATION

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