



CHF Solutions, Inc. (NASDAQ: CHFS)

Annual Meeting of Stockholders

May 25, 2017

# 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.*

*Although the Company believes that the forward-looking statements are reasonable and based on information currently available, it can give no assurances that the Company's expectations are correct. All forward looking statements are expressly qualified in their entirety by this cautionary statement.*

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

# 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

# Aquadex Business Overview

## Business and Product 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

## Aquadex 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 four largest cardiology societies have published guidelines recommending ultrafiltration



Aquadex Console



Venous Catheter



Blood Circuit Set

A photograph of a doctor in a white lab coat and stethoscope, holding and interacting with a tablet computer. The image is overlaid with a semi-transparent dark blue filter.

# Market Opportunity

# Heart Failure's Significant Burden

## Congestive Heart Failure

- ~ 5 million people annually in the U.S. experience congestive heart failure
- 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

## Symptoms and Treatment of Fluid Overload

### Symptoms

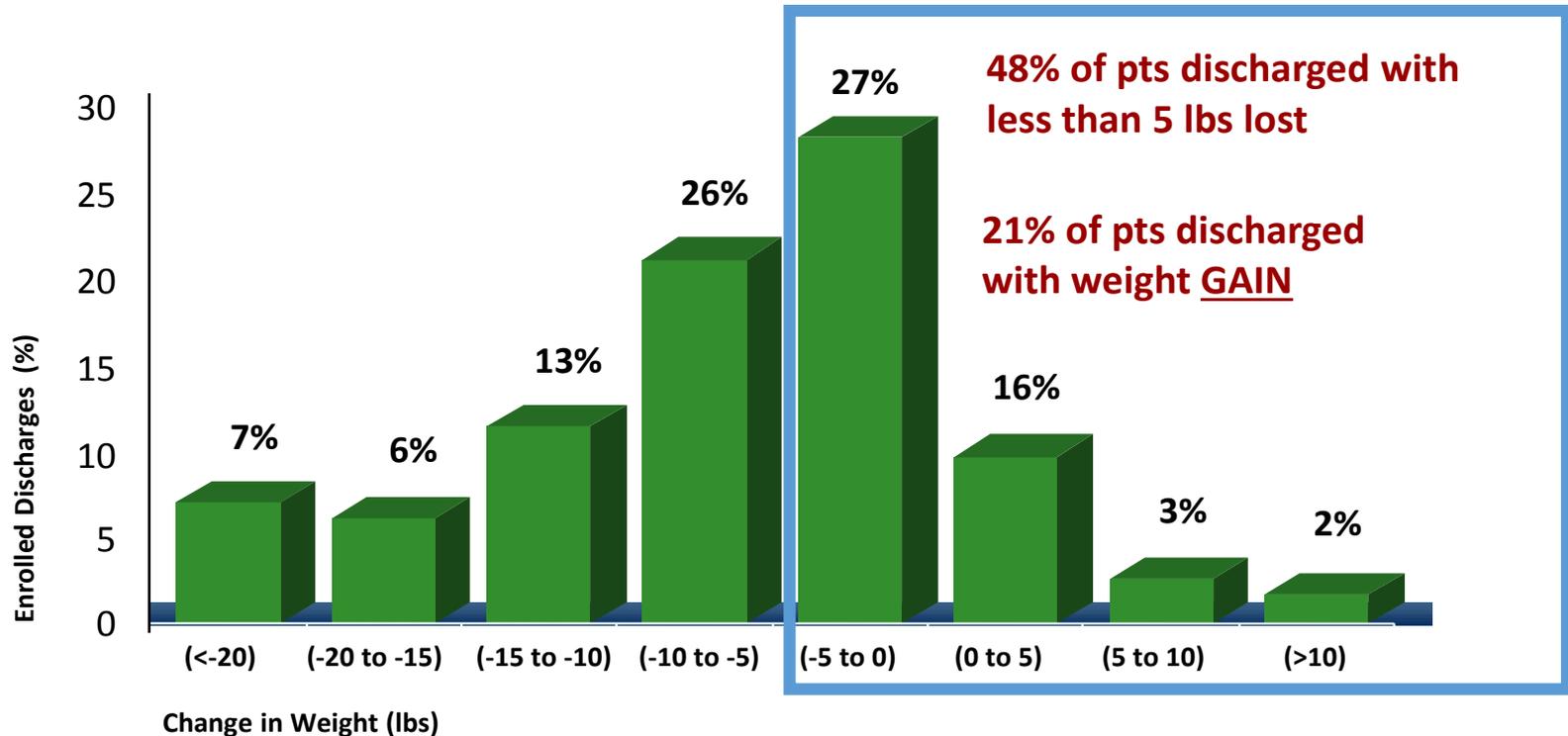
- Increased weight gain, particularly over short period
- Swelling in legs and arms
- Fluid in abdomen
- Difficulty in breathing and shortness of breath

### Treatment

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

# ADHERE Registry: Weight at Discharge

Change in Weight During Hospitalization  
January 2001 to April 2006 (n=96,094)



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

# Affordable Care Act

- Hospital Readmission Reduction Program effective as of Oct 1, 2012 (FY 2013)
- Requires CMS to reduce payments to hospitals with excess heart failure readmissions, among other conditions
- **Penalty:** hospitals can lose  $\leq 3\%$  of total Medicare reimbursement †

Readmission Data	Readmission Rate
30 day readmissions	22% <sup>1</sup>
6 month readmissions	44% <sup>2,3</sup>

Admitted patients with  
Emergency Department as  
first point of care: 78%<sup>4</sup>

†Readmission Penalties Source: 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.

1. Centers for Medicare & Medicaid Services. Hospital Compare datasets. National Rate (READM\_30\_HF); 3Q2011 – 2Q2014. <https://data.medicare.gov/data/hospital-compare>. Accessed June 10, 2016.
2. Krumholtz HM et. al. *Arch Intern Med*. 1997 Jan 13;157(1): 99-104.
3. Ross JS, et al. *Circ Heart Fail*. 2010 Jan; 3(1): 97-103.
4. Gheorghide M, Filippatos G. *Eur Heart J*. 2005 Mar 15; 7 (Suppl): B13-B19.

A photograph of a light blue AquaDex FlexFlow medical device. The device features a large color touchscreen at the top displaying a software interface with various data fields and graphs. Below the screen is a control panel with several buttons, including a prominent red 'Stop' button and a green 'Start' button. The device is mounted on a stand and has various cables connected to its side.

# 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



# Aquapheresis Therapy

- A simplified form of ultrafiltration (UF)
  - Removes both salt and water
- Safe method to achieve euvolemia (dry weight)
- Ease of Use
  - Highly automated setup and operation
  - Inpatient or outpatient settings
  - Peripheral or central venous access
  - Used often with 4:1 RN ratios in Stepdown
  - Ambulatory capabilities



# Aquadex FlexFlow Console & Circuit

- Simple operator interface (two user settings) and tailored treatment
- rate of withdrawal, 10 to 40ml/min. in 5ml increments
- the desired rate of fluid removal, 10 to 500ml/hour in 10ml increments
- Peripheral venous access and a transportable console (with battery) allows the patient to move about during treatment
- List price = \$28,500
- 33cc of blood extracorporeal in circuit
- Blood is extracorporeal <1 minute
- Access typically via peripheral vein in the arm, central access an option and two OTN capable
- No impact on electrolyte balance, heart rate or blood pressure
- List price = \$900



# A Viable Option When Diuretics Fail

- Aquapheresis provides complete control over rate and total volume of fluid removed
- Ultrafiltration removes more than twice the amount of salt for a given fluid volume than IV Diuretics over a similar time period
- After Ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored<sup>1</sup>
- Ultrafiltration effectively and safely decreases Length-of-stay (LOS) and readmissions<sup>2</sup>

*Patient outcome data with Aquapheresis included fewer days in the hospital, fewer emergency room, and unscheduled office visits.<sup>3</sup>*

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

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

3. Costanzo MR, et al. *J Am Coll Cardiol*. 2007 Feb 13; 49(6): 675-683.

# A Single Center Experience

## Good Samaritan Hospital – Dayton, OH

- Independent study on 67 patients who received Aquapheresis
  - No 30-day readmissions for volume overload
    - 62% of patients were not readmitted after Aquapheresis therapy for 8 months
  - Average of 5.7L removed per patient
  - Length-of-Stay when started within 24 hours was 2.2 days compared to national average of 4.9 for comparable time period<sup>1</sup>
  - With the introduction of Aquapheresis therapy, readmission rates dropped from 12% to 4%

<sup>1</sup>Center for Disease Control (CDC.gov) - <http://www.cdc.gov/diabetes/statistics/cvdhosp/hf/fig2.htm>

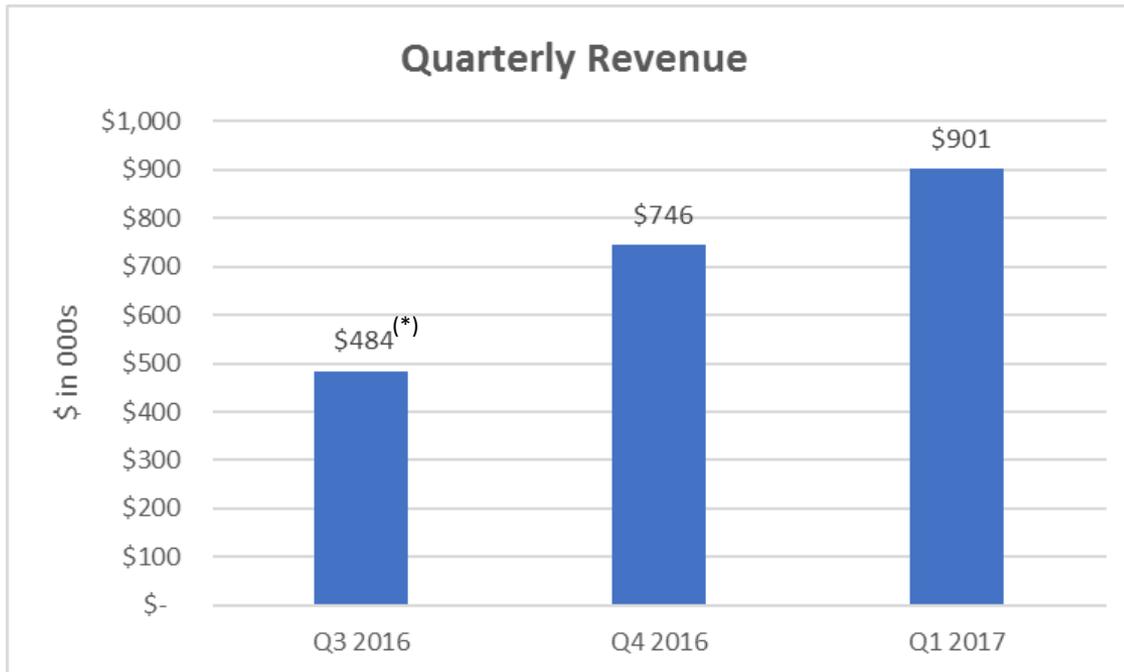
Single Hospital Experience Source: Poster presented at National Teaching Institute & Critical Care Exposition (NTI), Chicago, IL, May 5-8, 2008. Peterangelo M. *Prog Cardiovasc Nurs.* 2008 Fall; 23(4):168-172.

A photograph of a light blue AquaDex FlexFlow medical device. The device features a large color touchscreen at the top displaying a software interface with various data points and graphs. Below the screen is a control panel with several buttons and a dial. The device is connected to various cables and hoses. The background is a dark, textured surface.

# Aquadex Revenue Overview

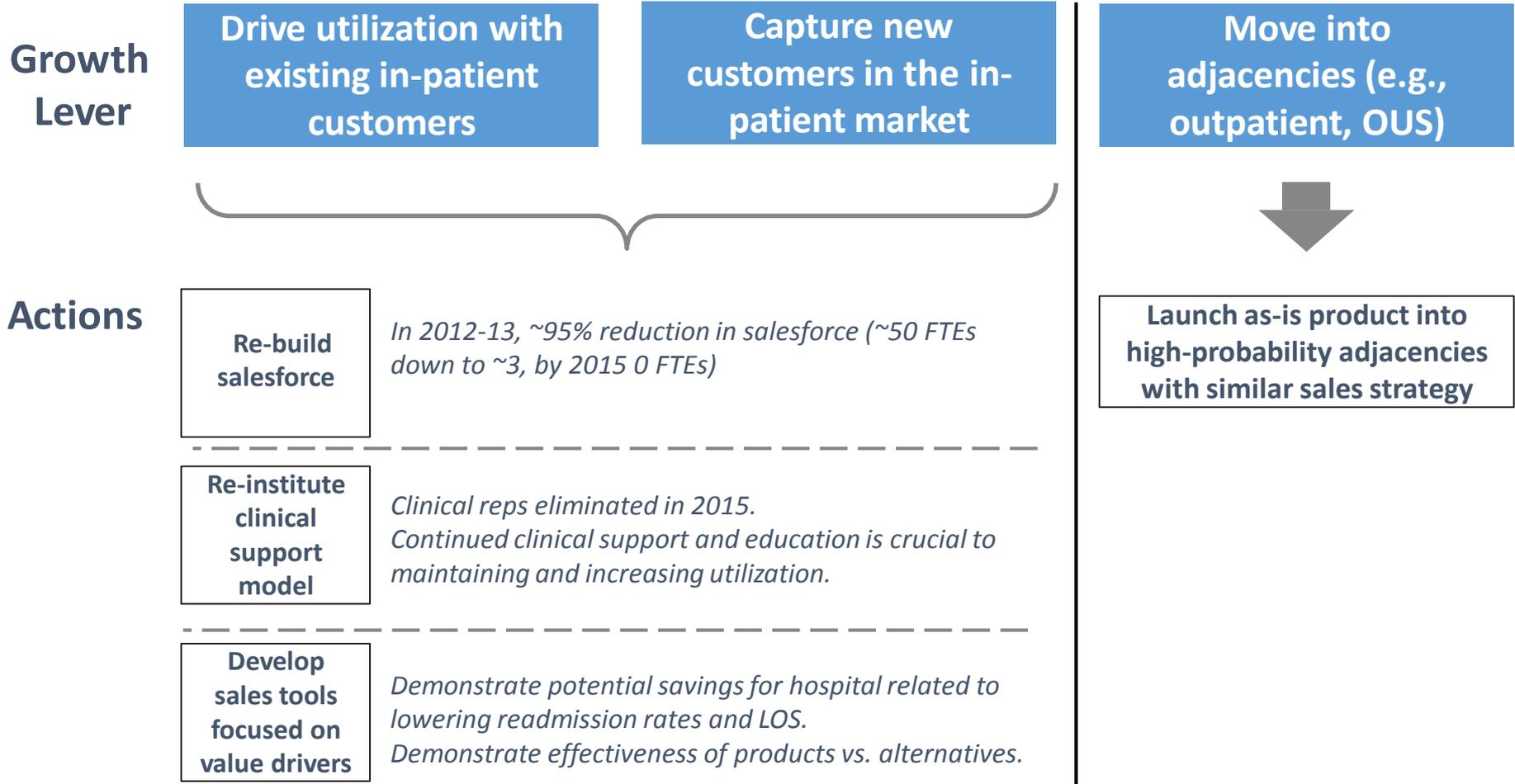
# Revenue (\$,000)

The acquisition of the Aquadex business in August 2016 coupled with management's new business strategy has resulted in increasing revenues.



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

# Grow Revenue with Existing & New Customers



**Sources:** Management, Gambro.com/Aquapheresis, UNLOAD trial

# Re-engaging & Revitalizing Hospital Accounts

- In August of 2016, 55 US hospital accounts accounted for 80% of revenue
- At year-end 2016, we had 95 hospitals that were purchasing products or services
- By the end of Q1-17, there are 115 hospital accounts that had ordered product or service
- Today we have 140 US hospitals that have ordered products or services

# Clinical Trials

Trial	Overview	Conclusions and Additional Considerations
SAFE: Journal of Cardiac Failure 2003; 9(3):227-31	<ul style="list-style-type: none"> <li>The Safe trial was a prospective observational study to verify the safety and function of the Aquadex system as an alternative ultrafiltration treatment that does not require a central venous catheter</li> </ul>	<ul style="list-style-type: none"> <li>Rapid removal of extracellular and intravascular fluid volume excess can be safely achieved via peripherally inserted ultrafiltration (Aquadex) without the need for central venous catheter placement.</li> </ul>
RAPID: J Am Coll Cardiol 2005; 46(11): 2043-6	<ul style="list-style-type: none"> <li>Rapid was a randomized controlled trial to assess the safety and efficacy of ultrafiltration in patients admitted with decompensated congestive heart failure.</li> </ul>	<ul style="list-style-type: none"> <li>The study concluded that early application of UF for patients with CHF was feasible, well-tolerated, and resulted in significant weight loss and fluid removal.</li> </ul>
EUPHORIA: J Am Coll Cardiol 2005;46 (11):2047-51	<ul style="list-style-type: none"> <li>Euphoria sought to determine if ultrafiltration before intravenous diuretics in patients with decompensated heart failure and diuretic resistance results in euvoolemia and early discharge without hypotension or worsening renal function.</li> </ul>	<ul style="list-style-type: none"> <li>Ultrafiltration before IV diuretics effectively and safely decreases length of stay and readmissions. Clinical benefits persist at three months.</li> <li>Early ultrafiltration in patients with fluid overload and diuretic resistance permitted the discharge of 60% of high-risk ADHF patients in &lt;3 days.</li> <li>Aggressive fluid withdrawal (8,500 ml) with ultrafiltration was not associated with worsening renal failure, electrolyte abnormalities, or symptomatic hypotension</li> </ul>
UNLOAD: J Am Coll Cardiol 2007;49 (6):675-83	<ul style="list-style-type: none"> <li>The Unload trial was a randomized multicenter trial of early ultrafiltration versus intravenous diuretics in 200 patients hospitalized with heart failure and hypervolemia.</li> </ul>	<ul style="list-style-type: none"> <li>Ultrafiltration safely produces greater weight and fluid loss than intravenous diuretics.</li> <li>Ultrafiltration was associated with a 50% reduction in the number and length of hospital readmissions in the 90 days following the initial treatment.</li> </ul>
CARRESS: N Engl J Med. 2012;367:2296-2304	<ul style="list-style-type: none"> <li>Randomly assigned 188 patients with acute heart failure and worsened renal function</li> <li>The primary end point was the bivariate change in the serum creatinine level and body weight at 96 hours.</li> </ul>	<ul style="list-style-type: none"> <li>A stepped pharmacologic-therapy algorithm was superior to a strategy of ultrafiltration for the preservation of renal function at 96 hours, with a similar amount of weight loss with the two approaches</li> </ul>
		<p>Considerations</p> <ul style="list-style-type: none"> <li>The study population in this trial had more advanced disease than that which is indicated for Aquapheresis™</li> <li>Ultrafiltration was performed at a fluid-removal rate of 200 ml per hour, which may have been inappropriate for this patient population.</li> <li>Rates of intravascular volume refill were not monitored.</li> <li>Ultrafiltration was started a median of 8 hours after random assignment, placing ultrafiltration at a disadvantage in the 96 hour trial measurements relative to diuretics.</li> </ul>



# Aquapheresis Clinical Evidence: Guidelines

Society	Source	Recommendation / Key Findings
ACC / AHA - American College of Cardiology / American Heart Association	2013 ACCF/AHA Guideline for the Management of Heart Failure <sup>1</sup>	Ultrafiltration may be considered for patients with obvious volume overload to alleviate congestive symptoms and fluid weight. <b>(Level of Evidence: B)</b> Ultrafiltration may be considered for patients with refractory congestion not responding to medical therapy. <b>(Level of Evidence: C)</b>
HFSA - Heart Failure Society Of America	HFSA 2010 Comprehensive Heart Failure Practice Guidelines <sup>2</sup>	Ultrafiltration may be considered in lieu of diuretics. <b>(Strength of Evidence: B)</b>
ESC / HFA - European Society of Cardiology and Heart Failure Association	ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012 <sup>3</sup>	If an adequate diuresis cannot be achieved by doubling the dose of loop diuretic with dopamine and the patient remains in pulmonary oedema, venovenous isolated ultrafiltration should be considered.
CCS - Canadian Cardiovascular Society	2012 Canadian Cardiovascular Society Heart Failure Management Guidelines Update <sup>4</sup>	Patients with persistent congestion despite diuretic therapy, with or without impaired renal function, may, under experienced supervision, receive continuous venovenous ultrafiltration.

\* Sunshine Heart 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.

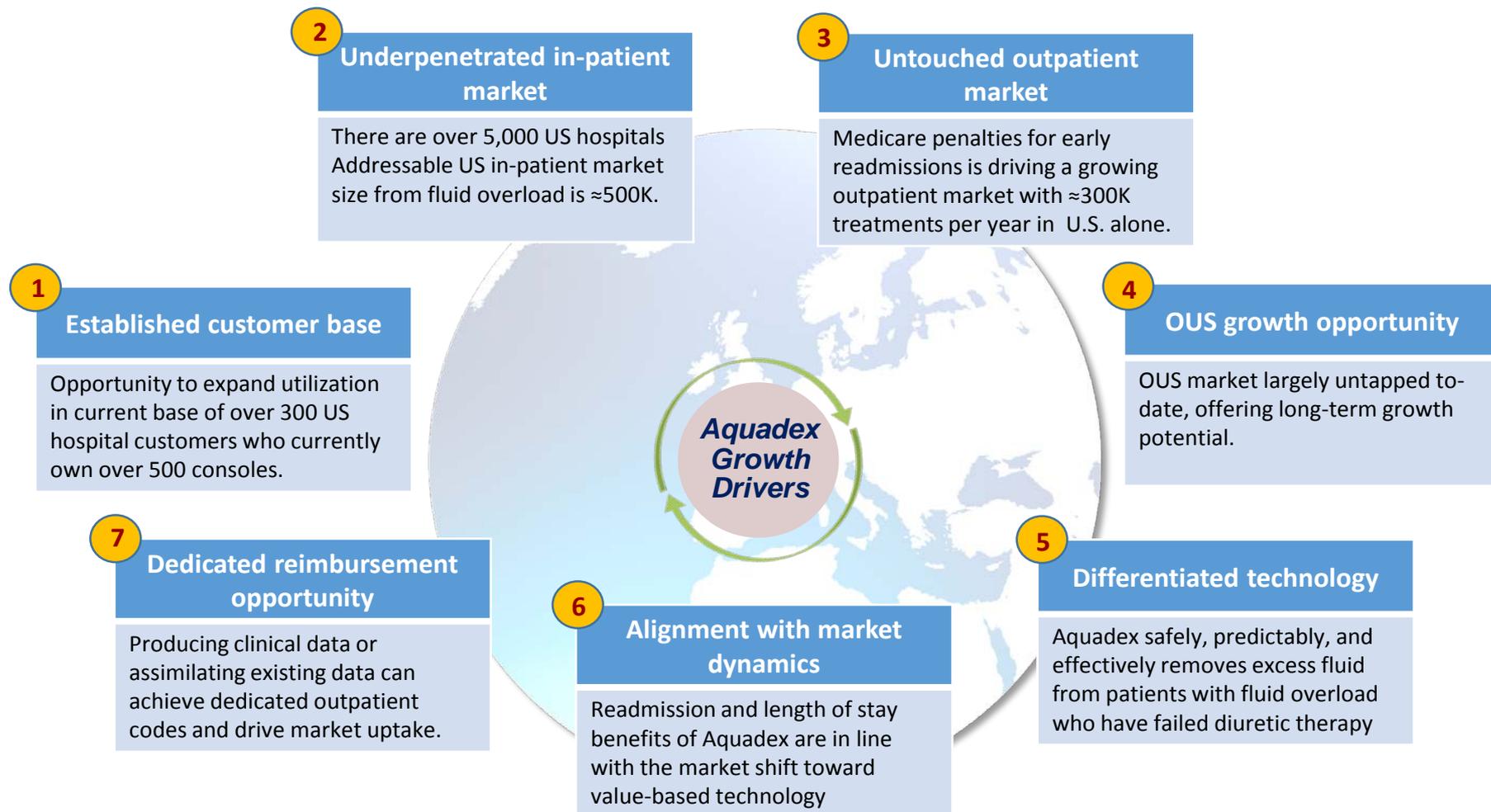
1. Yancy CW, et al. *J Am Coll Cardiol*. 2013 Oct 15; 62(16): e147 – e239.

2. Lindenfeld J, et al. *J Card Fail*. 2010 Jun; 16(6): 475 – 539.

3. McMurray JJ, et al. *Eur Heart J*. 2012 Jul; 33(14): 1787 – 1847.

4. McKelvie RS, et al. *Can J Cardiol*. 2013 Feb; 29(2): 168 – 181.

# Growth Opportunities



Thank you