



# Corporate Presentation

(NASDAQ: CHFS)

December 2018



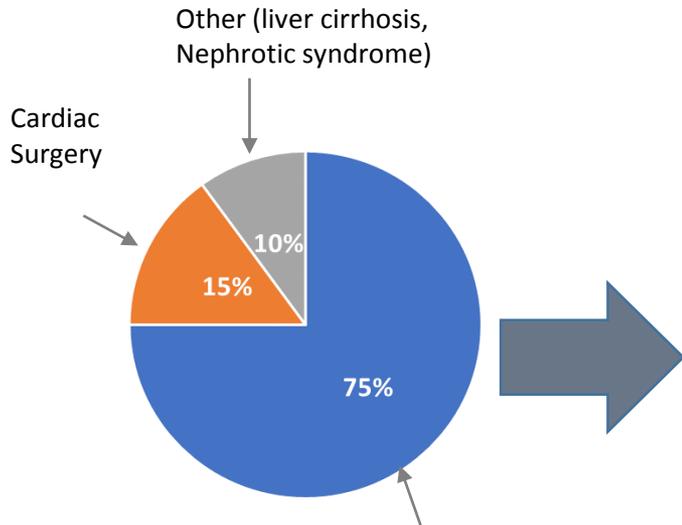
# Safe Harbor Statement

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 commercial strategy and to grow our Aquadex FlexFlow 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 FlexFlow 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 ("SEC"), including our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. 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.

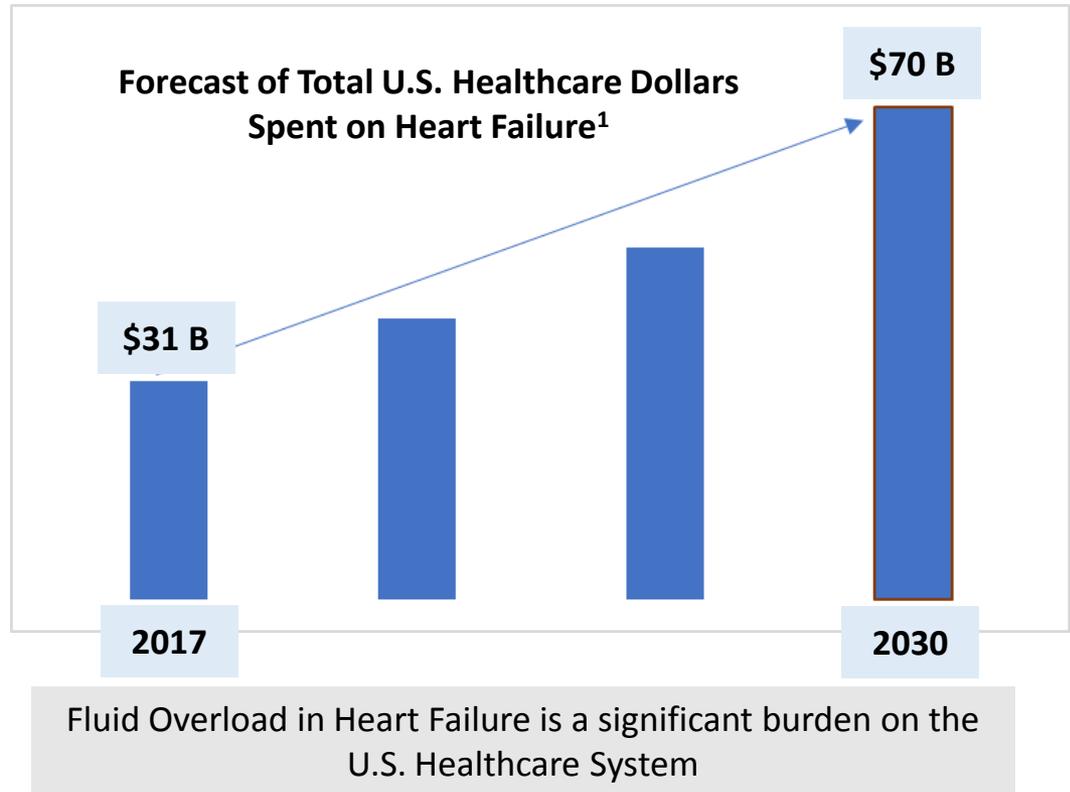
This presentation also contains estimates and other statistical data made by independent parties and by us relating to market shares and other data about our industry. These data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

*Aquadex Flex Flow® is a registered trademark of CHF Solutions, Inc.*

# Fluid Management Market Size is Large and Growing



Congestive Heart Failure (CHF) represents approx. 75% of total U.S. Fluid Management market<sup>2</sup>



Fluid Overload in Heart Failure is a significant burden on the U.S. Healthcare System

**Congestive Heart Failure (CHF) is the leading cause of fluid overload– and is the Company’s primary disease target**

<sup>1</sup> Circ Heart Fail. 2013 May

<sup>2</sup> McKinsey study internal document 2012

# Fluid Overload in Heart Failure Patients is Overwhelming

6.5M

- U.S. patients with HF and expected to rise to 8M patients by 2030<sup>1,2</sup>
- HF is the largest driver of Medicare costs

>1 M

- Annual U.S. and EU heart failure hospitalizations<sup>3</sup>
- Congestion (fluid overload) is primary cause<sup>3</sup>

90%

- Heart failure hospitalizations are due to fluid overload<sup>3</sup>

<sup>1</sup> Benjamin EJ. et al, 2017 Update: A Report from the American Heart Association. Circulation. 2017; 135(10):e146-e603

<sup>2</sup> Savarese G, Lund L, Card Fail Rev. 2017; 3(1): 7-11

<sup>3</sup> Costanzo MR, et al. J Am Coll Cardiol. 2017;69(19):2428-2445.

# Diuretics are the Standard of Care, but Fail to Provide Optimal Outcomes in Many Patients

- 40% Of patients demonstrate **diuretic resistance** (“failure”) and 68% show **sub-optimal response**<sup>1</sup>
- 68% Of HF patients are discharged from the hospital with residual excess fluid<sup>2</sup>
  - Worsening heart failure with **increased mortality** after discharge
  - Insufficient symptom relief, such as **persistent congestion**
  - Increase in **re-hospitalization** rates
  - Risk of **electrolyte imbalance** (i.e. low magnesium and low potassium)



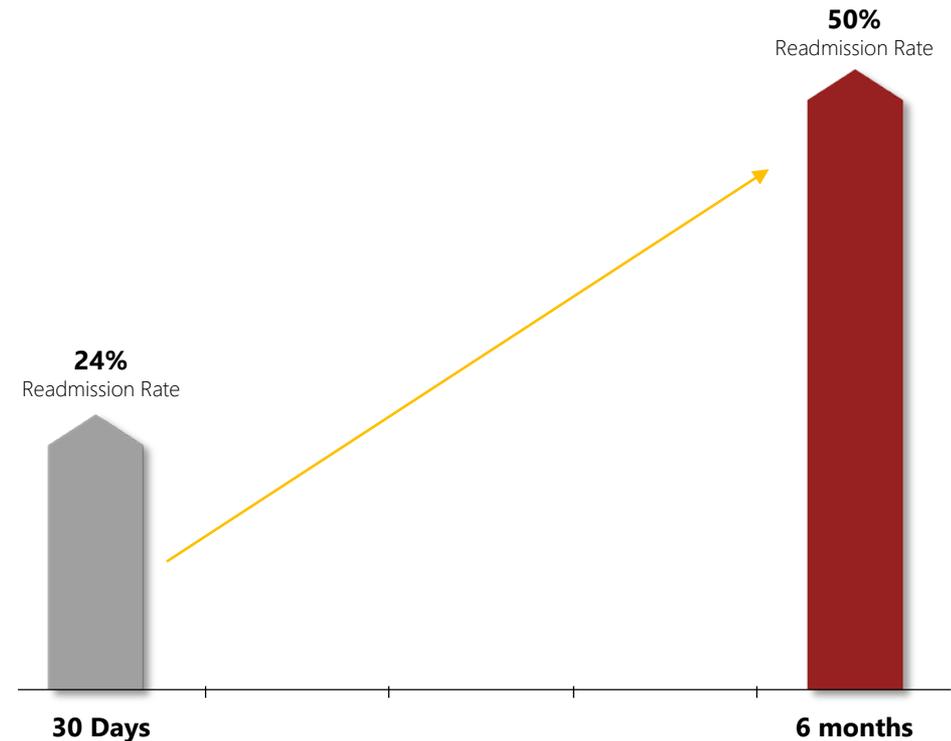
<sup>1</sup> Testani, Circ Heart Failure, 2016;9:e002370

<sup>2</sup> Costanzo MR, et al., J Am Coll Cardiol., 2017; 69: 2428-45

# Fluid Overload in HF Patients is a Recurrent Problem

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

- 24% Of patients are readmitted within 30 days of hospital release<sup>1</sup>
- 50% Of patients are readmitted within 6 months of hospital discharge<sup>1</sup>
- Adds to the economic cost burden



<sup>1</sup> Costanzo MR, et al. J Am Coll Cardiol. 2017 May 16;69(19):2428-2445

# Medicare Penalizes Hospitals with Excessive HF Readmissions

In 2012 the Affordable Care Act instituted the Hospital Readmission Reduction Program<sup>1</sup>

- **Requirement:** CMS to reduce payments to hospitals with excess readmissions
- **Penalty:** hospitals can lose  $\leq 3\%$  of Medicare reimbursement on all admissions
- **2017 Update** from Journal American Medical Association (JAMA):<sup>2</sup>
  - **Decrease in heart failure related readmissions but increase in 30-day and 1 year mortality rates**

<sup>1</sup> Readmissions Reduction Program (HRRP). Centers for Medicare & Medicaid Services website. Updated April 18, 2016. Accessed May 25, 2016.

<sup>2</sup> Journal of the American Medical Association (JAMA), November 2017



# Aquadex FlexFlow® System

## A Solution to this Unmet Clinical Need

- 40% More fluid removal than conventional diuretic drug therapy over the same period of time<sup>1</sup>
- No clinically significant impact on electrolytes balance, blood pressure, or heart rate<sup>1,2</sup>
- 53% Reduction in the risk of rehospitalization than those treated solely with diuretics at 90 days<sup>3</sup>
- Fewer re-hospitalization days due to cardiovascular event<sup>4</sup>

<sup>1</sup> Bart BA, et. al., *Am Coll Cardiol.*, 2005;46:2043–6

<sup>2</sup> Jaski BE et al. *J Card Fail.* 2003; 9(3):227-231

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

<sup>4</sup> Costanzo MR, et. al., *J Am Coll Cardiol.*, 2005;46:2047–51.



# The Value and Utility Advantages of Aquadex FlexFlow® are Compelling

- **Safe, effective, and clinically proven** to remove excess salt and water from the body
- Rapid and predictable rate of fluid removal
- Efficient patient to nurse workflow
- Prescribed by any medical specialty
- Customizable therapy plan based on provider's clinical goals for their patient



# Compelling Clinical Results Demonstrate the Potential of Aquadex FlexFlow®

## Good Samaritan Hospital- A Single Center Experience

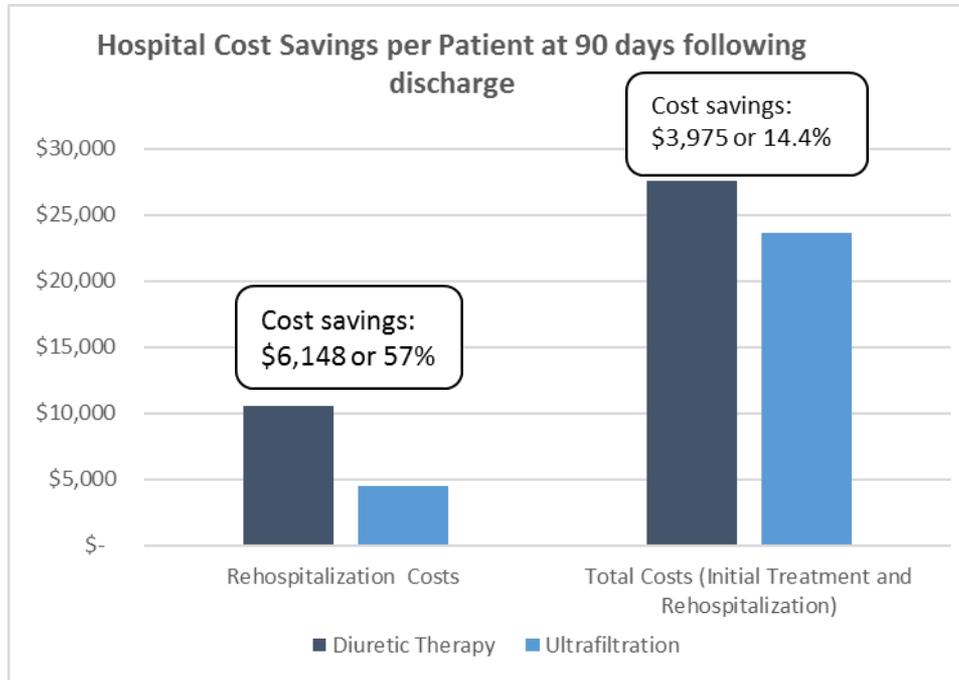
Independent study of 67 heart failure patients who received aquapheresis:

- No 30-day readmits for volume overload
- Length of stay when started within 24 hours was 2.2 days, compared to national average of 5.9 days
- Readmission rate from before aquapheresis down from 12% to 4% the year prior
- Average of 5.7 liters removed per patient

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



# New Data Shows Ultrafiltration Therapy Demonstrates a Cost Savings at 90 Days



Cost savings from reduced hospital readmission days were **\$3,975 (14.4%)** at 90-days:

- IV Diuretics costs: \$27,608
- Ultrafiltration costs: \$23,633

Despite higher up-front costs, ultrafiltration reduces hospital readmission rates and duration, which substantially lowers costs over a 90-day period compared to IV diuretics.

Costanzo MR, et al. Ultrafiltration vs. Diuretics for the Treatment of Fluid Overload in Patients with Heart Failure: A Hospital Cost Analysis. Poster presented at the ISPOR International Meeting, May 19-23, 2018, Baltimore, MD, USA

# Clinical Guidelines Support Use of Ultrafiltration



## **ACC/AHA – American College of Cardiology/ American Heart Association<sup>1</sup>**

Ultrafiltration may be considered for patients with obvious volume overload to alleviate congestive symptoms and fluid weight, or with refractory congestion not responding to medical therapy

## **HFSA - Heart Failure Society Of America<sup>2</sup>**

Ultrafiltration may be considered in lieu of diuretics

## **ESC / HFA - European Society of Cardiology and Heart Failure Association<sup>3</sup>**

Venovenous isolated ultrafiltration is sometimes used to remove fluid in patients with HF, although is usually reserved for those unresponsive or resistant to diuretics

## **CCS - Canadian Cardiovascular Society<sup>4</sup>**

Patients with persistent congestion despite diuretic therapy, with or without impaired renal function, may, under experienced supervision, receive continuous venovenous ultrafiltration

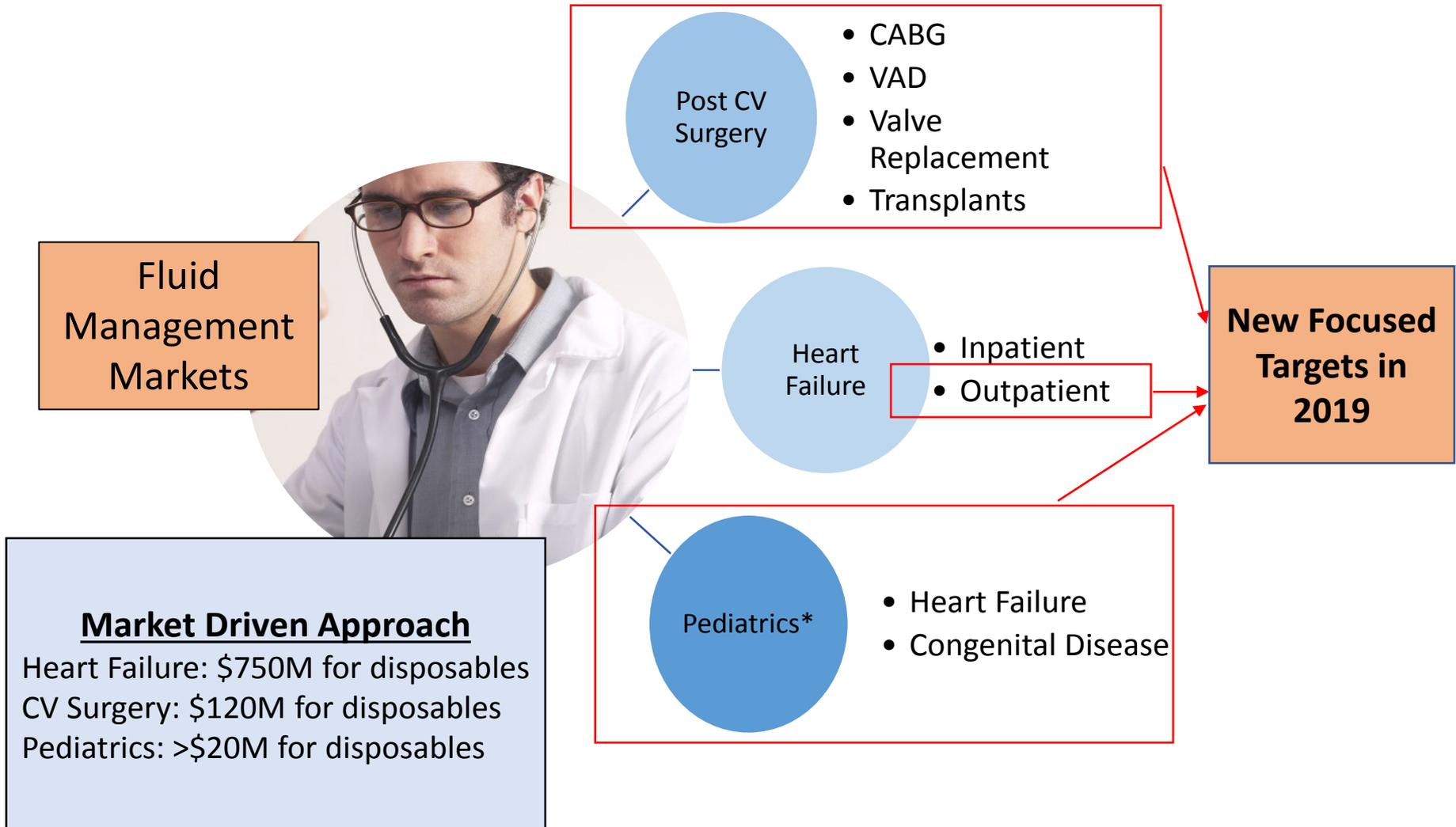
<sup>1</sup> Yancy CW, et al. *J Am Coll Cardiol*. 2013 Oct 15; 62(16): e147-e239.

<sup>2</sup> HFSA 2010 Comprehensive Heart Failure Practice Guidelines: Lindenfeld J, et al. *J Card Fail*. 2010 Jun; 16(6): 475 – 539.

<sup>3</sup> ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: McMurray JJ, et al. *Eur Heart J*. 2012 Jul; 33(14): 1787 – 1847.

<sup>4</sup> 2012 Canadian Cardiovascular Society Heart Failure Management Guidelines Update: McKelvie RS, et al. *Can J Cardiol*. 2013 Feb; 29(2): 168 – 181.

# Current & Future Target Markets



\* Subject to regulatory clearance

# New Market Opportunity – Cardio-Vascular Surgery

- 7.3M Cardiovascular operations and procedures per year in the US<sup>1</sup>
  - 500,000+ Coronary Artery Bypass Grafts (CABG) per year in US<sup>2</sup>
  - 80,000 Valve procedures per year in US<sup>3</sup>
- 4-6 Liters of fluid added to maintain cardiac output and blood pressure to accommodate anesthesia and bypass machine<sup>4</sup>
- CV surgery is being safely performed on patients 80+ years due to advances in cardiopulmonary bypass techniques



<sup>1</sup> National Center for Health Statistics 2009

<sup>2</sup> Coronary Artery Bypass Graft (CABG) Market Analysis By Type (Saphenous Vein Grafts, Internal Thoracic Artery Grafts), By Surgical Procedures, By Technology (On-Pump CABG, Off-Pump CABG), And Segment Forecasts, 2018 – 2025, Grand View Research

<sup>3</sup> iData Research: <https://idataresearch.com/over-182000-heart-valve-replacements-per-year-in-the-united-states/>

<sup>4</sup> Pradeep A, Rajagopalam S, Kolli AK, et al. HSR Proceedings in Intensive Care and Cardio Anesth 2010; 2: 287-296

# Multiple CV Surgical Procedures & Multiple Prescribers

- Aquadex FlexFlow® therapy can be used after cardiac procedures to remove fluid overload when diuretics fail
  - Valve repair or replacement
  - CABG (Coronary Artery Bypass Graft)
  - LVAD (Left Ventricular Assist Device) Implant
  - Heart Transplant
- Prescribers can include:
  - CT Surgeons
  - Surgical PA
  - Intensivists
  - Cardiologist



# CV Surgery Post Operative Complications Are Significant

- Volume Overload – Due to IV fluids and medication inhibits healing
- Potential acute kidney injury from bypass machine and anesthesia
  - Affects up to 30% of patients<sup>1</sup>
  - Fluid overload and rises in serum creatinine associated with longer ICU stays and increased mortality<sup>2</sup>
- Prolonged intubation
  - Excessive fluid and pulmonary edema causes respiratory issues
  - Associated with increased mortality<sup>3</sup>

<sup>1</sup> O'Neal JB, Shaw AD, Billings FT (2016) Acute kidney injury following cardiac surgery: current understanding and future directions. *Crit Care* 20(1):187.  
doi: [10.1186/s13054-016-1352-z](https://doi.org/10.1186/s13054-016-1352-z)

<sup>2</sup> Stein A, de Souza LV, Belettini CR, Menegazzo WR, Viégas JR, Costa Pereira EM, et al. Fluid overload and changes in serum creatinine after cardiac surgery: predictors of mortality and longer intensive care stay. A prospective cohort study. *Crit Care*. 2012;16:R99

<sup>3</sup> Federico Pappalardo, Annalisa Franco, Giovanni Landoni, Paola Cardano, Alberto Zangrillo, Ottavio Alfieri; Long-term outcome and quality of life of patients requiring prolonged mechanical ventilation after cardiac surgery, *European Journal of Cardio-Thoracic Surgery*, Volume 25, Issue 4, 1 April 2004, Pages 548–552, <https://doi.org/10.1016/j.ejcts.2003.11.034>

# CHF Solutions' Business Overview

- Aquadex FlexFlow® therapy is ultrafiltration to reduce fluid overload in patients, when diuretics fail
- Designed to be used by cardiologists early in the heart failure treatment protocol
- Growing opportunity in treating fluid overloaded patients post CV surgery
- Acquired from Baxter in August 2016 and now manufacturing all products in our Eden Prairie, MN facility
- FDA 510(k) market cleared; sold internationally with the CE mark
- Recently expanded US sales team to 13 sales territories and 5 clinical specialists
- Distribution partners in UK, Italy, Germany, Spain, Singapore, Hong Kong and Thailand



# Aquadex FlexFlow® Product Overview

## Aquadex FlexFlow Console



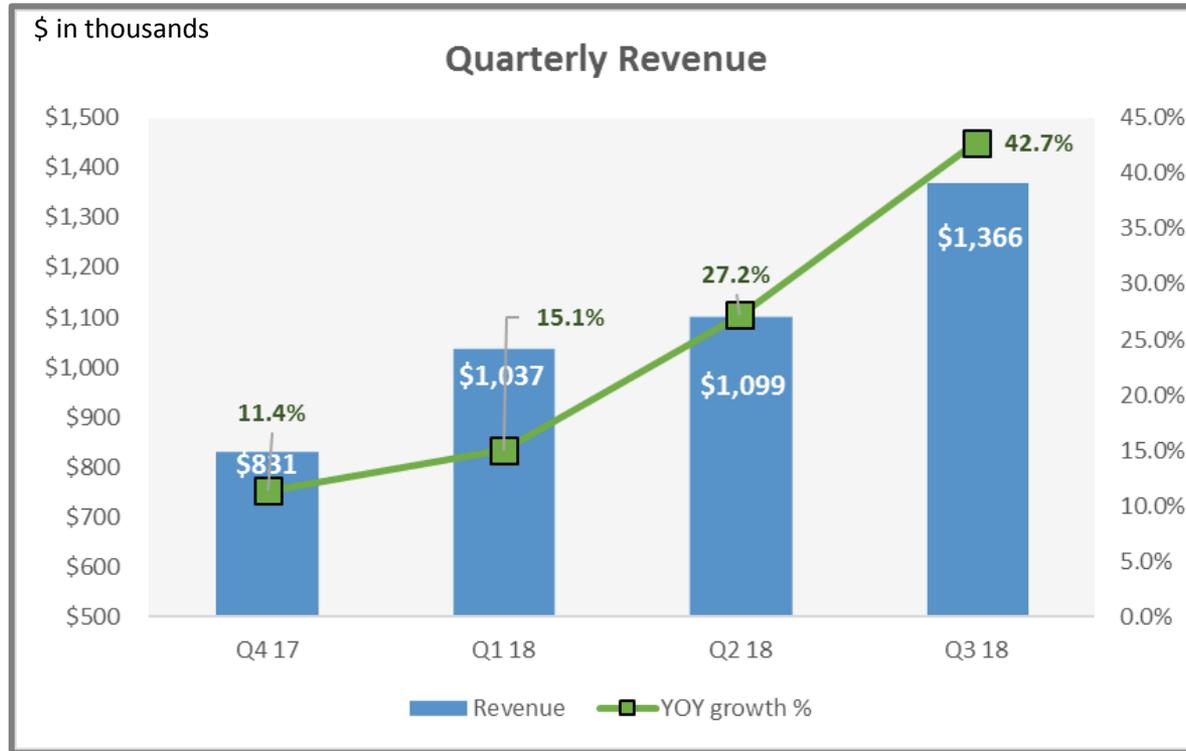
## Blood Circuit Set



## Dual Lumen venous catheter



# Revenue Performance



We have delivered double-digit year over year quarterly growth for the last 6 quarters

# Capitalization Table

**As of September 30, 2018**

<b>Instrument</b>	<b>Shares</b>	<b>Comments</b>
<b>Common Shares</b>	<b>7,074,407</b>	<b>Nasdaq: CHFS</b>
<b>Common Stock Equivalents</b>		
Series F Convertible Preferred	266,680	Convertible at \$2.12; anti-dilution rights
Warrants, Series F	7,760,400	EP \$2.12; Exp Nov. 2019-Nov. 2024
Warrants, Series F	265,816	EP \$4.50; Exp Nov. 2018-Nov. 2024
Warrants, all other	496,468	WAEP \$26.10; Exp Feb. 2022-Feb 2025
Options	1,987,502	WAEP \$4.90
RSUs	90	
<b>Total</b>	<b>10,776,944</b>	
<b>Fully Diluted Shares</b>	<b>17,851,351</b>	

# Key Growth Opportunities Exist

## Aquadex FlexFlow® Growth Drivers

- 1 Established Customer Base**  
Opportunity to expand utilization within our current customer base
- 2 Underpenetrated Inpatient Market**  
900,000 annual U.S. HF admissions for fluid overload, 68% achieving sub-optimal results with diuretics provide an inpatient opportunity of  $\geq 600,000$  patients/year
- 3 Untapped Outpatient Market**  
Medicare penalties for early readmissions is driving a growing outpatient market with  $\approx 300,000$  treatments per year in U.S. alone
- 4 OUS Growth Opportunity**  
OUS market largely untapped to date, offering long-term growth potential
- 5 Multiple Clinical Applications**  
Aquadex FlexFlow removes excess fluid in patients with a variety of fluid management issues
- 6 Alignment with Market Dynamics**  
Readmission rates and length of stay benefits of Aquadex FlexFlow are in line with the market shift toward value-based technology
- 7 Dedicated Reimbursement Codes**  
Producing clinical data and assimilating existing data can achieve dedicated outpatient codes and drive market uptake



## For More Information

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