

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**Current Report Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **August 24, 2016**

SUNSHINE HEART, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation)

001-35312
(Commission File No.)

68-0533453
(IRS Employer
Identification No.)

12988 Valley View Road
Eden Prairie, Minnesota 55344
(Address of Principal Executive Offices) (Zip Code)

(952) 345-4200
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

Sunshine Heart, Inc. ("**Sunshine Heart**" or the "**Company**") previously announced that John L. Erb, its Chief Executive Officer and Chairman of the Board, will present at the investMnt Conference in Minneapolis, Minnesota on August 24, 2016 at 11:45 AM Central Time. The live webcast may be accessed on the Investors page of the Sunshine Heart website at <http://ir.sunshineheart.com/events.cfm>. An audio archive of the webcast will be available following the call on the Company's website. This Form 8-K is being furnished to the SEC to furnish the presentation materials attached as Exhibit 99.1 hereto.

In accordance with General Instruction B.2. of Form 8-K, this information, including Exhibit 99.1, is furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in this Current Report on Form 8-K will not be deemed an admission as to the materiality of any information that is required to be disclosed solely by Regulation FD.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Presentation by John L. Erb, Chief Executive Officer and Chairman of the Board of Sunshine Heart, Inc.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

Dated: August 24, 2016

SUNSHINE HEART, INC.

By: /S/ CLAUDIA DRAYTON

Name: Claudia Drayton

Title: Chief Financial Officer

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
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Company Update

investMnt Conference
Minneapolis, MN
August 24, 2016

FRM-04558-D

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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 timing, clinical enrollment, clinical results, financing availability, product sales and marketing or efficacy of products, 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, 2015.
- 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.
- Caution: C-Pulse® is an investigational device. The device is limited by federal (United States) law to investigational use only.
- C-Pulse is a registered trademark of Sunshine Heart Inc.

Executive Summary



- Focused on providing meaningful solutions for the \$95 billion Heart Failure market in two distinct ways:
 1. **Developing a fully implantable disruptive solution for Class III Heart Failure:**
 - Based on learnings from original C-Pulse device
 - Proprietary neuro based approach
 - Targets easy to find anatomical structures with immediate and measurable response
 - Can be developed in half the time and cost of previous pathway
 2. **Recent Acquisition of Aquadex FlexFlow® product line**
 - Strategically focused on serving fluid overload in HF patient
 - Unique proprietary ultrafiltration technology
 - Provides immediate profitable revenue and near-term cash flow

Executive Leadership Team



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



Molly Wade

Senior VP of Strategic Operations

- 15+ years experience in medical sales/marketing
- 7+ years start-up management experience
- B.S. University of Minnesota, Health Science/Marketing



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



Eric Lovett, PhD

VP Clinical Affairs

- 20+ years of clinical trial and medical technology experience
- Doctorate, Marquette University, Biomedical Engineering
- Post-doctorate, Cardiology/Autonomic Nervous System at Harvard's T.H. Chan School of Public Health



Dimitrios Georgakopoulos, PhD

Chief Scientific Officer

- Doctorate Johns Hopkins School of Public Health
- Post-Doctorate, Cardiology Johns Hopkins Hospital
- Experience in PV loops, hemodynamics, heart failure, neural control of the circulation



David Lerner

Senior VP, Research & Development

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

Discussion Outline



- HF Market Opportunity
- Neuromodular Strategy
- Aquadex FlexFlow Product Line
- Financial Priorities

Heart Failure is a Significant Economic Burden

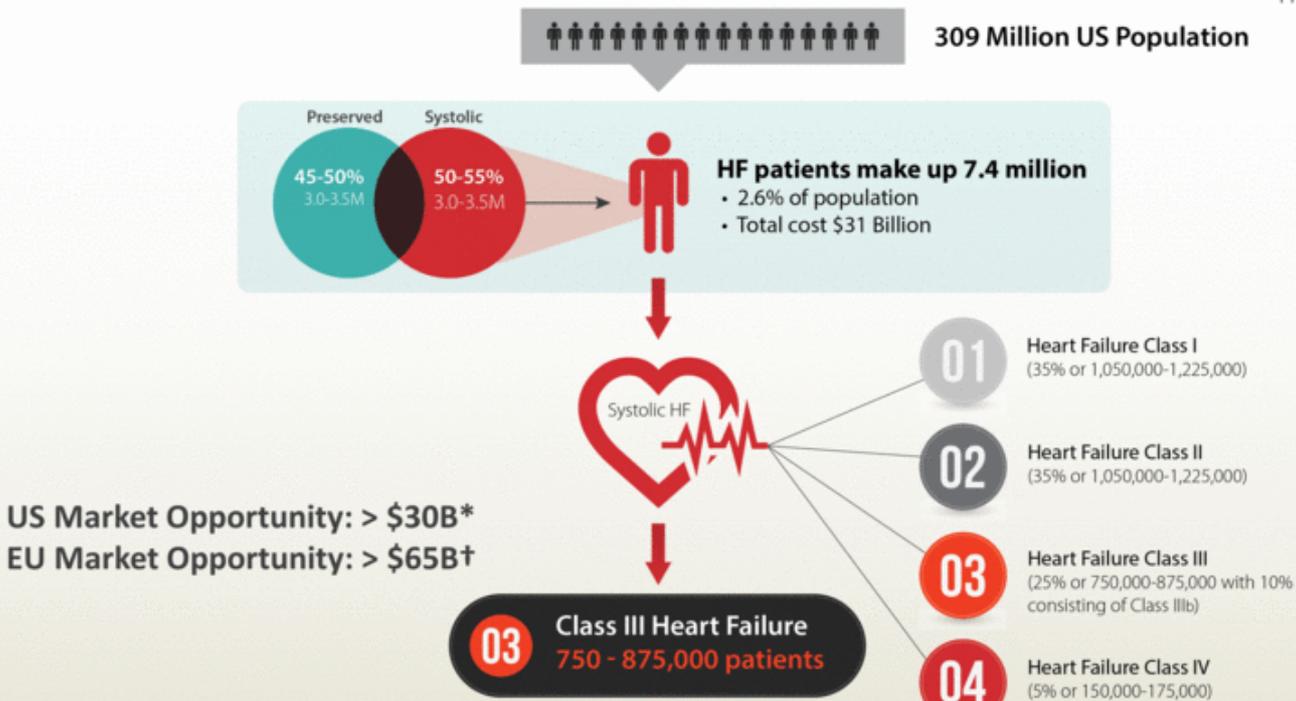


- Incidence: 800,000+ new cases per year*
- One of every 9 deaths*
- HF linked to other major diseases: Obesity, Diabetes, Hypertension*
- Mortality: 60%+ at 5 years, worse by NYHA class*
- > 1 million hospitalizations per year*
- More hospital days for HF than any other diagnosis*
- Coronary MI deaths are down by half but heart failure has almost tripled[†]
- 2025: number of HF patients estimated to increase to > 10 million*
- **U.S. cost expected to double from \$35B today to over \$70B by 2030 ***

*Source: Heidenreich Circ HF 2013-AHA Forecast

[†]Source: National Hospital Discharge Survey, CDC/NCHS and NHLBI

Current US Estimate of Heart Failure patients



*Source: Circulation 2014

† Source: Framingham Study, Windover 2007 Report, AHA 2010 Stroke Update, HRI 2010

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Mechanical Counterpulsation: Our Original Focus



1. Increase diastolic pressure:
↑ Coronary Blood Flow
2. Unloading of the left ventricle
3. Maintenance of mean aortic pressure
4. Optimize left ventricular coupling

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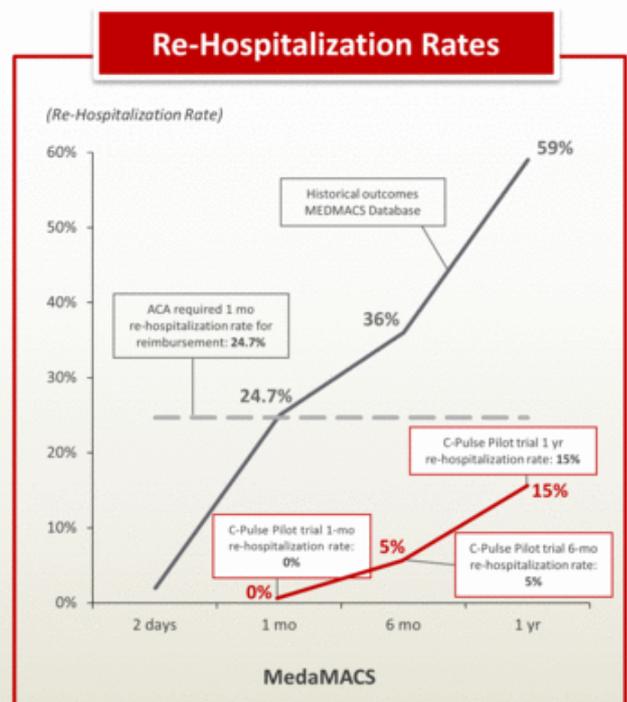
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Clinically Significant Results: Reduction in Heart Failure Readmissions



Readmission Rates	3-mo	6-mo	12-mo
Class III Average	25%	36%	59%
C-Pulse Feasibility	0	5%	15%

- Meaningful readmission reductions at 3, 6, and 12 months
- Significant financial upside for Hospitals & Payers



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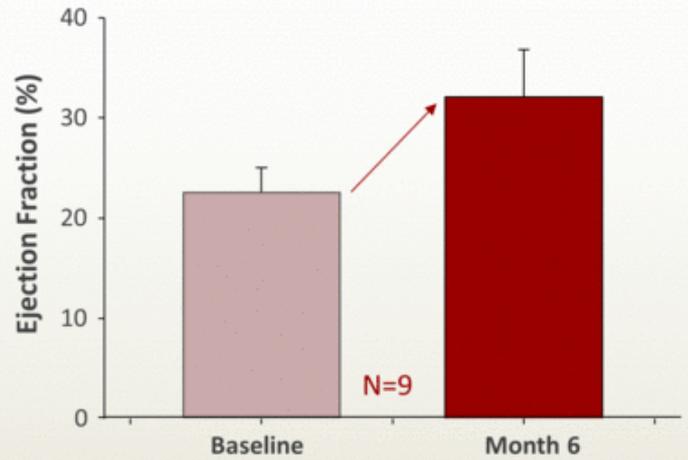
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Clinically Significant Results: Improvement in Cardiac Structure



OPTIONS HF: European Post-Market Study

- 15 patients implanted in Europe
- Mean increase of 10 EF units (%), implying improved patient outcomes; CRT increases 2.7 units*
- Four patients weaned from therapy due to HF stabilization
- Significant improvements in 6 minute walk, NYHA class and quality of life as demonstrated by KCCQ and MLWHF



*Source:
Kramer DG et al., J Am Coll Cardiol. 2010;56:392-406.

Hemodynamic Improvement Greater than Expected from Mechanical Counterpulsation



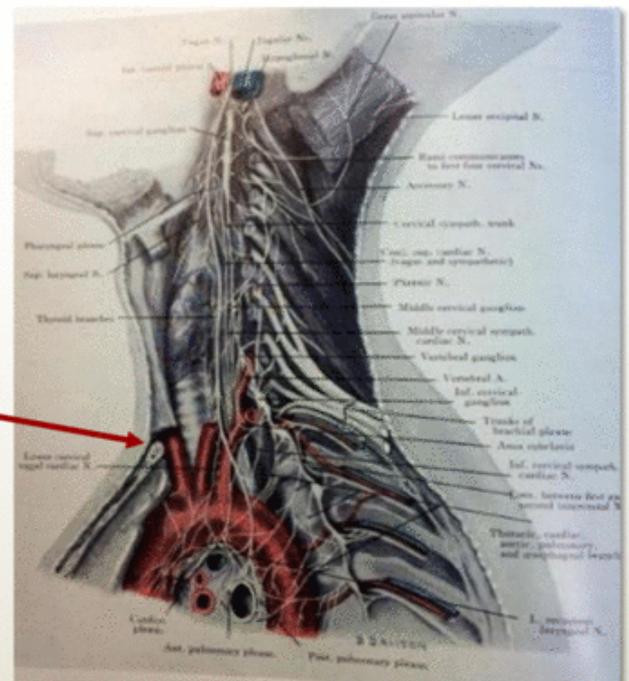
Original Hypothesis: C-Pulse results driven by bio-mechanical flow improvement

Clinical Benefit: More positive than predicted by mechanical action alone

Observation: C-Pulse cuff placement on the Aortic Arch is the optimal location to activate aortic baroreceptors (neuro)

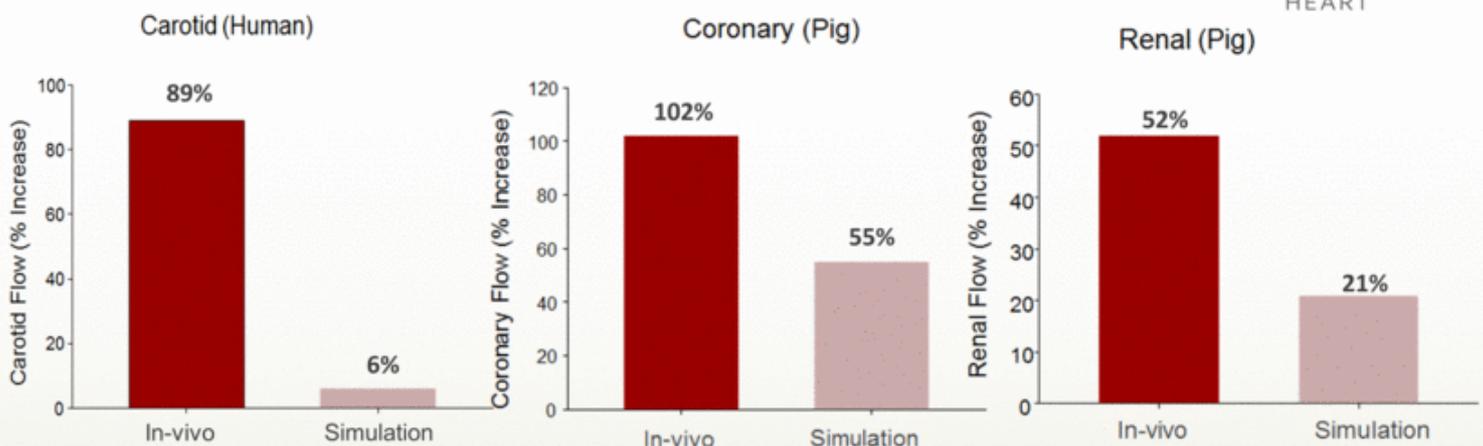
Question: What is the mechanism of action from counterpulsation causing the clinical benefit?

Answer: Compelling evidence the mechanism of action is neurally mediated



Mitchell GAG. Anatomy Autonomic Nervous System. 1953

Compelling Evidence of Neuromodulatory Impact

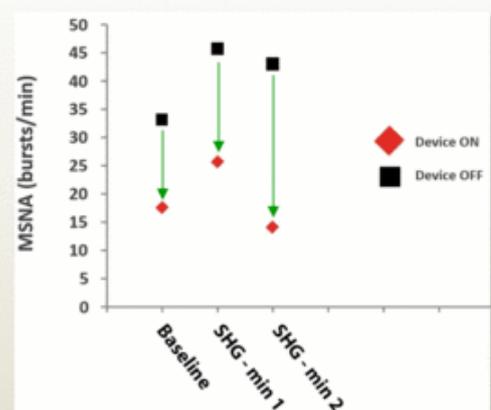


- Independent Assessment by Professor Patrick Segers who is a leader in the study of arterial hemodynamics in Ghent, Belgium
- Assessment using a validated computer model of the circulation without feedback control from the nervous system
- Carotid Flow increased in 4 patients by 89% compared to the predicted response of 6% via simulation
- Other in-vivo responses show similar findings, confirming that neuromodulation is the primary driver of clinical benefit

Positive Initial Neuro Assessment



- Positive patient outcomes from Dallas VA with investigator Dr. Phi Wieg led to a physician initiated study with Dr. William Cornwell and Dr. Ben Levine of University of Texas Southwestern
- Conducted an acute neuro and hemodynamic assessment of a patient who had been on counterpulsation therapy for 8 months
- **Demonstrated a greater than 50% reduction** in sympathetic nerve activity with the C-Pulse turned on versus off at baseline and during acute stress



Counterpulsation: Challenges of a Mechanical Approach

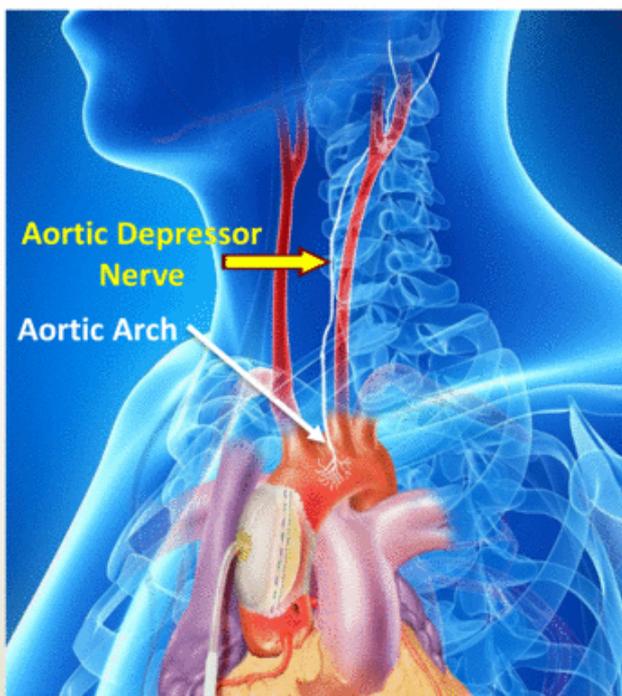
- Driveline limited inclusion criteria and enrollment rate
- Limited market in advanced HF patients
- Current C-Pulse system challenging for patients to manage long term
- R&D required for fully-implantable system lengthy and expensive



Neuromodulatory Approach: A Much Better Path

- Less R&D for fully implantable compared to counterpulsation
- Pathway to commercialization is faster and easier
- Increases access to larger NYHA Class III market
- Proprietary technology in place; building strong IP protection

Innovative Neuromodulation Approach



Minimally Invasive: 2 small incisions

1. IPG Pocket
2. 1-2 inch neck exposure

Easy: Nerve Cuff Placement on one of only two distinct & complementary afferent baroreceptor sites (Aortic Depressor Nerve)

Fast: 45 - 60 min procedure

Value: Procedural LOS < 1 day in hospital

Flexible: Multiple anesthetic regimens

Proprietary: Provisional patent in place

Near-Term

- **Purpose:** Publication revealing that neuromodulation is the mechanism driving clinical improvements
- n=5 with original CP-1 device; sympathetic nerve activity with C-Pulse ON vs. OFF
- Enrollment underway; complete follow-up in 2016

Neuro FIM

- **Purpose:** First-in-man demonstrating acute feasibility of Fully-Implantable System
- n=20 utilizing external pulse generator and prototype leads
- Enrollment begins and follow-up complete Q4 2016

Fully Implantable

- **Purpose:** Establish chronic benefits of fully-implantable system
- Implantable pulse generator (OEM) and proprietary leads
- N=30, 6-month follow-up to support CE Mark and IDE/PMA submissions
- Enrollment begins 1H 2017 / complete 1H 2018 / CE Mark: 2018

Our Approach is Well Positioned for Clinical Success

5 Criteria for Long-Term Success

- 1. Easily Identifiable Target: Confirmed in Cadaver Studies**
 - Aortic Depressor Nerve identified in neck by Prof. John Karemaker
- 2. Easily Separable Target**
 - Nerves are anatomically distinct from other structures
- 3. Clear and Immediate Biomarker of Effect**
 - Stimulation induces changes in heart rate and vascular properties that are immediate and obvious
- 4. Mechanism of Action is direct, simple and well understood**
 - Baroreflex is well studied and understood
 - Our technology stimulates the two main afferent nerves activating Baroreflex
- 5. Decades of Experience in Humans**
 - Afferent nerve stimulation studies in the 1960's-1980's with profound response
 - SSH alliance with with Dr. Tim Peters and Prof. Cornelius Borst, who personally conducted many of these studies

Our Approach Seeks to Benefit Multiple Stakeholders



- **Patient Benefits**
 - Improved duration and Quality of Life
 - Reduced readmissions and time in hospital
 - Implant to discharge within 24 hours
 - Significantly delay the need for later stage, more invasive therapies
- **Physician Benefits**
 - Minimally-invasive implant < 1 hour
 - Therapy addresses entire Heart Failure spectrum
- **Healthcare System Benefits**
 - Reduced penalties for readmissions
 - Significantly shorten HF hospitalized days
 - Cost-effective solution for HF epidemic
 - Estimated cost of US healthcare \$70 Billion in 2030 mandating new, economically viable therapies*

**Source: Heidenreich Circ HF 2013-AHA Forecast*

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Discussion Outline



- HF Market Opportunity
- Neuromodular Strategy
- **Aquadex FlexFlow Product Line**
- Financial Priorities

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Aquadex FlexFlow Overview

- Acquired from Baxter International (8/5/16)
- This is the former CHF Solutions Inc. business *
- Installed base of over 500 Aquadex consoles
- 300+ hospitals have purchased Aquadex
- Operationally Ready: 7 fully-trained Therapy Development Specialists
- Historical Revenue: \$13M in 2013 and ~\$4M in 2014, 2015
- Revenue Projections:
 - 2016: exit at a \$5M annualized quarterly run rate
 - 2017: exit at a \$10M annualized quarterly revenue rate



*CHF Solutions sold to Gambro in 2010; Gambro sold to Baxter in 2013

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Aquadex FlexFlow Product Line



Disposable peripheral Catheter



Aquadex Console



Disposable, single-use Blood Set

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Aquadex FlexFlow

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



Aquadex FlexFlow

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

All treatments must be administered by a healthcare provider, under physician prescription, both of whom having received training in extracorporeal therapies.

Capable of removing up to 4 liters of isotonic fluid (water and sodium) per 8 hour treatment



Fluid Overload Drives Increased Heart Failure Costs



- Congestive heart failure is the leading cause of hospitalizations¹
 - Annual incidence of HF is 10 per 1,000 (pts over 65 years of age)²
- **90% of HF patients present with symptoms of fluid overload³**
 - Almost 1 million hospitalizations annually in US for acute HF⁴
 - Average hospital stay is ≈5 days⁵
 - Re-hospitalization rates during the six months following discharge up to 50%^{6,7}

Total cost of heart failure in the US is projected to increase from \$31 billion in 2012 to \$70 billion in 2030⁸

1. Gheorghiade M et al. *Am J Med* 2006 Dec; 119(12 Suppl 1):S3-S10.
2. Mozaffarian D, et al. *Circulation*. 2016 Jan 26; 133(4): e38-e360.
3. Costanzo MR, et al. *J Am Coll Cardiol*. 2007 Feb 13; 49(6): 675-683.
4. Gheorghiade M, Filippatos G. *Eur Heart J*. 2005 Mar 15; 7 (Suppl): B13-B19.

5. Chen J, et al. *J Am Coll Cardiol*. 2013 Mar 12; 61(10): 1078-1088.
6. Ross JS, et al. *Circ Heart Fail*. 2010 Jan; 3(1): 97-103.
7. Desai AS, Stevenson LW. *Circulation*. 2012 Jul 24; 126(4): 501-506.
8. Heidenreich PA, et al. *Circ Heart Fail*. 2013 May; 6(3): 606-619.

Discussion Outline



- HF Market Opportunity
- Neuromodular Strategy
- Aquadex FlexFlow Product Line
- **Financial Priorities**

Financial Results and Key Balance Sheet Information



Operations Summary	Year ended Dec 31, 2014	Year ended Dec 31, 2015	Q2 2015	Q2 2016
Net Loss	\$(25.6M)	\$(26.7M)	\$(6.4M)	\$(4.2M)
Loss per share	\$(1.51)	\$(1.47)	\$(0.35)	\$(0.23)
Cash used in Operations	\$(22.6M)	\$(23.0M)	\$(5.7M)	\$(3.4M)

Summary Balance Sheet	Dec. 31, 2015	Q2 2016
Cash & Cash Equivalents:	\$23.1M	\$12.0M
Long-term Debt (*)	\$8.0M	\$6.1M
Total Stockholders' Equity:	\$12.2M	\$3.7M

(*) Repaid in full on August 4, 2016. Entered into a new \$5.0M credit facility with Silicon Valley Bank on August 5, 2016.

Key Financial Priorities



- **Reduce cash burn**
 - Operations streamlined to extend cash runway
 - Resources prioritized for development of fully implantable
- **Raise capital to finance the development of the fully implantable system**
 - \$3.5 million in convertible preferred shares - July 2016
 - Additional capital raise in Fall 2016 to fund neuromodulation strategy



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Thank you