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SSH

Annual Report





Our objective is to  
improve the  
quality of life for  
patients with heart  
failure and related  
conditions

Dear Shareholders,

After acquiring the Aquadex FlexFlow® system and product portfolio from Baxter International in August of 2016, we began executing a revenue growth strategy in deliberate stages. In fourth quarter of 2016, we focused on increasing utilization in the top 55 hospital accounts that provided about 80 percent of the revenue stream in 2015. Furthermore, we expanded our efforts to re-engage an additional 110 hospitals that also purchased blood sets in 2015.

By the end of 2016, there were 95 hospital accounts that have re-engaged and are purchasing the disposable blood sets on a regular basis. Through the end of first quarter 2017, a total of 115 active hospitals are ordering disposable product regularly. Our momentum is increasing as we enhance visibility in previously dormant accounts while the Aquadex business was operated under previous ownership.

Looking ahead to 2017 and beyond, the company will focus on four key areas:

- Provide better diagnostic tools that will enable healthcare professionals to improve patient selection
- Generate meaningful economic evidence to support reimbursement and drive utilization
- Expand the utilization of Aquadex in other areas of the hospital
- Expand the use of the Aquadex system in an outpatient setting

In addition to these key focus areas, we are excited about some early initiatives that involve collecting post-market clinical data by partnering with high-profile institutions to accomplish this effort. We will have more to update on this activity later in 2017. We remain confident that the initiatives in place, coupled with increasing the number of sales personnel to enhance national coverage, will provide steady growth to meet company objectives.

John Erb,  
Chief Executive Officer and Chairman of the Board  
April 10, 2017



# Sunshine Heart Business Overview

## Aquadex FlexFlow System

### AN EFFECTIVE TREATMENT FOR FLUID OVERLOAD

The Aquadex FlexFlow is designed to simply, safely, and precisely remove excess fluid (primarily excess salt and water) from patients suffering from fluid overload who have failed diuretic therapy. With the Aquadex FlexFlow, medical practitioners can specify and control the amount of fluid to be extracted at a safe, predictable, and effective rate. The Aquadex system has been shown to have no clinically significant impact on electrolyte balance, blood pressure or heart rate.<sup>1</sup>

### Advantages of Aquadex

- Removes isotonic fluid via ultrafiltration - extracts more than diuretic therapy while sparing potassium and magnesium<sup>2</sup>
- Simple to use, highly automated, and provides complete control over rate and total volume of fluid removed
- Effectively and safely decreases length of stay and hospital readmissions<sup>3</sup>



## Clinical Evidence

### A HISTORY OF CLINICAL EVIDENCE

Ultrafiltration (UF) is the leading method for removing excess salt and water to relieve congestion in patients with heart failure and other related conditions. Several trials including SAFE, the preliminary safety and efficacy study, demonstrated fluid removal goals were achievable in 92% of patients. Both RAPID-HF and UNLOAD demonstrated clinical benefit of UF as compared to usual care (diuretics). The UNLOAD trial showed that patients had 38% greater weight loss, 50% reduction in total number of re-hospitalizations, 52% reduction in Emergency Department or clinic visits, and 63% total reduction in days re-hospitalized.

The CARRESS trial showed a rise in creatinine among renal patients on a fixed UF treatment strategy as compared to diuretics, although levels normalized at 7 days post treatment with no difference in body weight, re-hospitalization rates or mortality between the two approaches.

In summary, UF is an acceptable method for addressing HF and fluid overloaded patients.

## Aquadex Growth Drivers

### PREPARING FOR THE FUTURE

- 1 **Grow the HF Outpatient Market:** Continue supporting outpatient usage and expansion to include collaborations and programs aimed at decreasing readmission rates and hospital stay.
- 2 **Enhance the HF Inpatient Market:** Over one million hospitalizations annually in US for acute HF with 90% presenting fluid overload.<sup>4</sup>
- 3 **Expansion into other applicable therapies**
- 4 **Reimbursement Opportunity:** Working to build acceptance through clinical evidence to gain reimbursement for Aquapheresis therapy.

### Board of Directors

John L. Erb (Chairman)  
Jon W. Salvesson  
Gregory D. Waller  
Warren S. Watson  
Matthew Likens  
Steve Brandt

### Corporate Officers

John L. Erb  
*Chief Executive Officer*  
  
Claudia Napal Drayton  
*Chief Financial Officer*

### Transfer Agent and Registrar

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Brooklyn, NY 11219  
Website: [www.amstock.com](http://www.amstock.com)  
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### Company Secretary

Claudia Napal Drayton

### Company Headquarters

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### Independent Registered Public Accounting Firm

Ernst & Young LLP  
Minneapolis, MN

## ANNUAL MEETING

May 25, 2017



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## Rx Only

**Indication:** The Aquadex FlexFlow® System is indicated for temporary (up to 8 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.

### References from inside back cover:

1. SAFE Trial: Jaski BE, et al. J Card Fail. 2003 Jun; 9(3): 227-231; RAPID Trial: Bart BA, et al. J Am Coll Cardiol. 2005 Dec 6; 46(11): 2043-2046.
2. Ali SS, et al. Congest Heart Fail. 2009; 15(1):1-4.
3. Costanzo MR, et al. J Am Coll Cardiol. 2005 Dec 6; 46(11): 2047-2051.
4. Costanzo MR, et al. J Am Coll Cardiol. 2007 Feb 13; 49(6): 675-683.