

Sunshine Heart, Inc. (NASDAQ:SSH) Investor Presentation March 2017

www.sunshineheart.com

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.

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Statement about Free Writing Prospectus



- This presentation highlights basic information about us and the offering. Because it is a summary that has been prepared solely for
 informational purposes, it does not contain all of the information that you should consider before investing in our company. Except as
 otherwise indicated, this presentation speaks only as of the date hereof.
- This presentation does not constitute an offer to sell, nor a solicitation of an offer to buy, any securities by any person in any jurisdiction in
 which it is unlawful for such person to make such an offering or solicitation.
- Neither the Securities and Exchange Commission (the "SEC") nor any other regulatory body has approved or disapproved of our securities
 or passed upon the accuracy or adequacy of this presentation. Any representation to the contrary is a criminal offense.
- This presentation includes industry and market data that we obtained from industry publications and journals, third-party studies and surveys, internal company studies and surveys, and other publicly available information. Industry publications and surveys generally state that the information contained therein has been obtained from sources believed to be reliable. Although we believe the industry and market data to be reliable as of the date of this presentation, this information could prove to be inaccurate. Industry and market data could be wrong because of the method by which sources obtained their data and because information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties. In addition, we do not know all of the assumptions that were used in preparing the forecasts from the sources relied upon or cited herein.
- We have filed a Registration Statement on Form S-1 with the SEC, including a preliminary prospectus dated March 28, 2017 (the "Preliminary Prospectus"), with respect to the offering of our securities to which this communication relates. Before you invest, you should read the Preliminary Prospectus (including the risk factors described therein) and, when available, the final prospectus relating to the offering, and the other documents filed with the SEC and incorporated by reference into the Preliminary Prospectus, for more complete information about us and the offering. You may obtain these documents, including the Preliminary Prospectus, for free by visiting EDGAR on the SEC website at http://sec.gov.
- Alternatively, we or any underwriter participating in the offering will arrange to send you the prospectus if you request it by contacting Ladenburg Thalmann & Co. Inc., 570 Lexington Ave, 11th Floor, New York, NY 10022 or by email at prospectus@ladenburg.com.

Risk Factors



- An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties described below, in the Preliminary
 Prospectus 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.
- Our integration of the operations of the Aquadex Business requires significant efforts and we may need to allocate more resources to integration and product
 development activities than originally anticipated. These efforts will result in additional expenses and involve significant amounts of management's time. Our failure to
 manage and coordinate the growth of the company could also have an adverse impact on our business.
- Our near-term prospects are highly dependent on the development of a single product, the Aquadex FlexFlow, and we have no other commercial products or products in active development at this time. Failure to successfully commercialize Aquadex could have a material impact on our future operations.
- The established market or customer base for our Aquadex FlexFlow is limited and our success depends on our ability to increase adoption of the Aquadex FlexFlow.
 Failure to achieve sufficient market acceptance will significantly limit our ability to generate revenue and be profitable.
- We have no experience in commercially manufacturing the Aquadex FlexFlow and related components. As a result, we may not be able to develop and implement
 efficient, low-cost manufacturing capabilities and processes that will enable us to manufacture the Aquadex FlexFlow or related components in significant volumes.
- We will rely on third-party suppliers, including single source suppliers, to provide us with certain components of the Aquadex FlexFlow and to provide key components
 or supplies for use with our products. Any failure by our suppliers could have a material impact on our business.
- The number of shares of common stock underlying our outstanding warrants is significant in relation to our currently outstanding common stock and could cause downward pressure on the market price for our common stock and conversion of such outstanding convertible securities will cause dilution to holders of our common stock.
- We have incurred operating losses since our inception and anticipate that we will continue to incur operating losses in the near-term. The report of our independent
 registered public accounting firm issued in connection with its audit of our financial statements for the fiscal year ended December 31, 2016 expresses substantial
 doubt about our ability to continue as a going concern.
- On November 11, 2016, we received notice from the Staff that we no longer satisfied Nasdaq Listing Rule 5550(b) insofar as we did not expect to report stockholders' equity of at least \$2.5 million upon the filing of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 and that the deficiency could serve as an additional basis for the delisting of the Company's common stock from The Nasdaq Capital Market. We have sought an extension of the March 20, 2017 compliance deadline; but we cannot assure you that Nasdaq will grant our extension request. While we believe that the proceeds from this offering will be sufficient to evidence compliance with the minimum stockholders' equity requirement of Nasdaq, we cannot assure you that we will be able to meet the minimum stockholders' equity requirement. If it appears to the Nasdaq staff that we will not be able to meet the minimum stockholders' equity or any other listing standard, our common stock may be subject to delisting.

Aquadex Business Overview

Business and Product Overview

- Sunshine Heart provides Aquadex and its Aquapheresis technology, a form of ultrafiltration to reduce fluids in patients, particularly when diuretics are not effective.
 - Acquired from Baxter in August 2016.
 - FDA 510(k) market cleared and CE marked.
 - Installed base of 500+ consoles and successfully used on over 60k patients
- Aquadex is used to treat fluid overload in congestive heart failure ("CHF") patients, a leading cause of hospitalization in the United States, particularly in those ages 65+.



Aquadex Highlights

- Clinically proven to reduce 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.
- Aquadex realizes gross margins in excess of 70%



Aquadex Console

Venous Catheter

Blood Circuit Set

Executive Leadership Team





John Erb

Chief Executive Officer, Chairman

- · 40+ years experience in medical devices
- CE0 of 4 med-tech start-up companies
- Chairman of 3 public boards
- BA in Business Administration from California State University, Fullerton



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





Megan Brandt

VP of Regulatory Affairs and Quality Assurance

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

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

Currently recruiting a VP of Sales & Marketing



Sandra Eayrs

- VP of 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

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Board of Directors



John Erb

- Chief Executive Officer, Chairman
- 40+ years experience in medical devices
- CEO of 4 med-tech start-up companies ٠
- . Chairman of 3 public boards
- BA in Business Administration from California State University, Fullerton



Warren Watson Non-Executive Member

Matthew Likens

- · 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





- 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 from 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

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6



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Jon Salveson

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

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

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



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Aquapheresis Therapy

SUNSHINE HEART

- A <u>simplified</u> 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



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A Viable Option When Diuretics Fail



9

- Aquapheresis provides complete control over rate and total volume of fluid removed
- After Ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored¹
- Ultrafiltration effectively and safely decreases Length-of-stay (LOS) and readmissions²

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

- 1. Marenzi G, et al. J Am Coll Cardiol. 2001 Oct; 38(4): 963-968.
- Costanzo MR, et al. J Am Coll Cordiol. 2005 Dec 6; 46(11): 2047-2051.
 Costanzo MR, et al. J Am Coll Cordiol. 2007 Feb 13; 49(6): 675-683.

Aquapheresis Removes More Salt than Diuretics Alone



 Ultrafiltration removes isotonic fluid and therefore the greatest possible amount of sodium per unit of fluid withdrawn¹



No effect on serum electrolytes²

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Agostoni PG, et al. Cardiology. 2001; 96(3-4): 183-189.
 Kazory A. Clin J Am Soc Nephrol. 2013; 8(10): 1816-1828
 Bart BA, et al. J Am Coll Cardiol. 2005 Dec 6; 46(11): 2043-2046.

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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





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Upcoming Milestones



- Outpatient clinical evaluation designed to decrease readmission rates and length of hospital stay while improving quality of life
- A U.S. university has received FDA and IRB approval to move forward with an Investigational Device Exemption (IDE) pivotal study. The investigation is limited to 8 US institutions and 45 US subjects studying the use of Aquadex FlexFlow (or ultrafiltration) in pediatrics
- US Registry for hospital observation units to support outpatient reimbursement to begin in Q3-17

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SHINE

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Actual Revenue (\$,000)





Grow Revenue with Existing and New Customers





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Re-engaging and Revitalizing Hospital Accounts



- In 2016, 55 hospital accounts accounted for 80% of revenue
- In Q1-17 there are 115 hospital accounts that have ordered product from Sunshine Heart
- 23 dormant accounts revitalized in Q1-17

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Reimbursement - Outpatient



- CMS established a new ICD-9 code (99.78) for Aquapheresis
- CPT code 36516, Physician reimbursement
 - Appropriate use of existing CPT 36516 Therapeutic Apheresis with extracorporeal selective adsorption or selective filtration and plasma re-infusion; reimbursement ≈ \$75.00-\$90.00
- APC 0112, Therapeutic Apheresis for Outpatient Clinic
 - CPT 36516 maps to APC 0112; reimbursement ≈ \$1,500 to \$3,600







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21

CHF is the Leading Cause of Fluid Overload

Defining the Market Opportunity



Causes of Fluid Overload	Symptoms and Treatment of Fluid Overloa	d
 High intake of sodium IV therapy Transfusion reaction as a result of blood 	 Increased weight gain, particularl short period Symptoms Swelling in legs and arms Fluid in abdomen 	y over
 Fluid remobilization after burn treatment Administration of hypertonic fluids, such as mannitol or hypertonic saline solution Administration of plasma proteins, such as albumin 	 Diuretic (e.g. Lasix/Furosemide) Secondary pharmacologics Ultrafiltration 	
	Congestive Heart Failure	
	 ~ 5 million people annually in the U.S. experience conges heart failure Weakening pumping ability of heart causes blood and flut to back up into the lungs 	stive uid
Congestive heart failure		
 Liver cirrhosis Nephrotic syndrome Corticosteroid therapy Hyperaldosteronism 		
	 Causes of Fluid Overload High intake of sodium IV therapy Transfusion reaction as a result of blood transfusions Fluid remobilization after burn treatment Administration of hypertonic fluids, such as mannitol or hypertonic saline solution Administration of plasma proteins, such as albumin Congestive heart failure Liver cirrhosis Nephrotic syndrome Corticosteroid therapy Hyperaldosteronism 	Causes of Fluid Overload Symptoms and Treatment of Fluid Overload • High intake of sodium • Increased weight gain, particularly short period • IV therapy • Swelling in legs and arms • Transfusion reaction as a result of blood transfusions • Fluid in abdomen • Fluid remobilization after burn treatment • Diuretic (e.g. Lasix/Furosemide) • Administration of hypertonic fluids, such as albumin • Diuretic (e.g. Lasix/Furosemide) • Congestive heart failure • Ultrafiltration • Congestive heart failure • Weakening pumping ability of heart causes blood and flut to back up into the lungs • Congestive heart failure • Weakening pumping ability of heart causes blood and flut to back up into the lungs

Sources: Portable Fluids and Electrolytes (Lippincott Williams & Wilkins 2007); MedlinePlus, Decision Resources PatientBase, American Heart Association



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ADHERE Registry: Weight at Discharge





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

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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 period¹
 - With the introduction of Aquapheresis therapy, readmission rates dropped from 12% to 4%

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

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24

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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 ≤ 3% of • total Medicare reimbursement t

Readmission Data	Readmission Rate
30 day readmissions	22% ¹
6 month readmissions	44% ^{2,3}
Admitted patients with Emergency Department as first point of care:	78%4

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

Centers for Medicare & Medicaid Services. Hospital Compare datasets. National Rate (READM_30_HF); 3Q2011 – 2Q2014. <u>https://data.medicare.gov/cata/hospital-compare</u>. Accessed June 10, 2016.
 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. Gheorghiade M, Filippatos G. Eur Heart J. 2005 Mar 15; 7 (Suppl): B13-B19.

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Aquadex Clinical Overview

Clinical Trials



Trial	Overview	Conclusions and Additional Considerations
SAFE: Journal of Cardiac Failure 2003; 9(3):227–31	 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 	 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.
RAPID: J Am Coli Cardiol 2005; 46(11): 2043–6	 Rapid was a randomized controlled trial to assess the safety and efficacy of ultrafiltration in patients admitted with decompensated congestive heart failure. 	 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.
EUPHORIA: J Am Coll Cardiol 2005;46 (11):2047-51	 Euphoria sought to determine if ultrafiltration before intravenous diuretics in patients with decompensated heart failure and diuretic resistance results in euvolemia and early discharge without hypotension or worsening renal function. 	 Ultrafiltration before IV diuretics effectively and safely decreases length of stay and readmissions. Clinical benefits persist at three months. Early ultrafiltration in patients with fluid overload and diuretic resistance permitted the discharge of 60% of high-risk ADHF patients in <3 days. Aggressive fluid withdrawal (8,500 ml) with ultrafiltration was not associated with worsening renal failure, electrolyte abnormalities, or symptomatic hypotension
UNLOAD: J Am Coll Cardiol 2007;49 (6):675–83	 The Unload trial was a randomized multicenter trial of early ultrafiltration versus intravenous diuretics in 200 patients hospitalized with heart failure and hypervolemia. 	 Ultrafiltration safely produces greater weight and fluid loss than intravenous diuretics. Ultrafiltration was associated with a 50% reduction in the number and length of hospital readmissions in the 90 days following the initial treatment.
CARRESS: N Engl J Med. 2012:367:2296- 2304	 Randomly assigned 188 patients with acute heart failure and worsened renal function The primary end point was the bivariate change in the serum creatinine level and body weight at 96 hours. 	 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 Considerations The study population in this trial had more advanced disease than that which is indicated for Aquapheresis[™] Ultrafiltration was performed at a fluid-removal rate of 200 ml per hour, which may have been inappropriate for this patient population. Rates of intravascular volume refill were not monitored. Ultrafiltration as started a median of 8 hours after random assignment, placing ultrafiltration at a disadvantage in the 96 hour trial measurements relative to diureti

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 ¹	Ultrafiltration may be considered for patients with obvious volume overload to alleviate congestive symptoms and fluid weight. (Level of Evidence: B) Ultrafiltration may be considered for patients with refractory congestion not responding to medical therapy. (Level of Evidence: C)
HFSA - Heart Failure Society Of America	HFSA 2010 Comprehensive Heart Failure Practice Guidelines ²	Ultrafiltration may be considered in lieu of diuretics. (Strength of Evidence: 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 ³	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 ⁴	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 Cordiol. 2013 Oct 15; 62[16]: e147 – e239. 2. Lindenfeld J, et al. J Cord Fail. 2010 Jun; 16(6): 475 – 539. McMurray JJ, et al. Eur Heart J. 2012 Jul; 33(14): 1787 – 1847.
 McKelvie RS, et al. Can J Cardial. 2013 Feb; 29(2): 168 – 181.

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Sunshine Heart US Registry Study Concept: Observation Unit ADHF Management





Outpatient

- High-risk patients self-identify with ADHF hospitalization .
- Salvageable cases diverted from Emergency Department to Observation Unit/Clinical Decision Unit for UF & subsequent release
- Early initiation of UF to maximize benefit
- Followed 90 Days from discharge for outcomes

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30



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Capitalization / Ownership Table Investment Considerations

Capitalization / Ownership Table



CAPITALIZATION TABLE (as of March 28, 2017)				
Securities	No. of shares			
Common shares outstanding	3,119,492			
Warrants (weighted average price \$4.05)	927,223			
Options (weighted average price \$81.27)	57,102			
Restricted Stock Units	10,465			
Total Fully Diluted Shares Outstanding	4,114,282			

Note: None of the warrants contain anti-dilution protection

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Thank you

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Fluid Overload Hospitalization



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Diuretic Therapy



What is Diuretic Therapy?

Diuretics are commonly known as "water pills" – they help your body get rid of unneeded water and salt through the urine

What is Failure of Diuretic Therapy?

- Diuretic failure criteria is established by the clinician or institution
- Examples include*:
 - Patient presents 10 lbs or more over dry weight
 - Previous hospitalizations where diuretic treatment was ineffective
 - Patient cannot achieve a goal of -2 liters at 24 hours
 - No significant difference in patient's global assessment of symptoms in 24 hours
 - Non-significant symptom improvement noted after escalating to high-dosing strategy
 - Observed worsening of renal function during diuretic treatment plan
 - Post and peri-operative fluid overload

*Sunshine heart takes no position with respect to the examples listed above.

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