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): **September 24, 2019**

CHF Solutions, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-35312**	**No. 68-0533453**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File Number)	**(I.R.S. Employer Identification No.)**

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	CHFS	Nasdaq Capital Market

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:

☐ 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure

CHF Solutions, Inc. (the ***"Company"***) previously announced that Claudia Drayton, its Chief Financial Officer, will present at the Ladenburg Thalmann 2019 Healthcare Conference on September 24, 2019 at 4:00 p.m. Eastern Time. 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. to Form 8-K, this information, including Exhibit 99.1, is furnished pursuant to Item 7.01 and shall not be deemed as "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 on this Current Report on Form 8-K will not be deemed as 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 Claudia Drayton, Chief Financial Officer of CHF Solutions, 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.

Date: September 24, 2019

CHF SOLUTIONS, INC.

By: /s/ Claudia Drayton
Name: Claudia Drayton
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Presentation by Claudia Drayton, Chief Financial Officer of CHF Solutions, Inc.

Exhibit 99.1

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Corporate Presentation

(NASDAQ: CHFS)
September 24, 2019

For Investor Purposes Only: Not For Product Promotion

Safe Harbor Statement

This presentation contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities and Exchange Act, as amended regarding our plans, expectations, beliefs, estimates, goals and outlook for the future that are intended to be covered by the Private Securities Litigation Reform Act of 1995. Except for statements of historical fact, all forward-looking statements are management's present expectations and are not guarantees of future events and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results to differ materially from those expressed in, or implied by, such forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "could," "would," "should," "plan," "predict," "potential," "project," "promising," "expect," "estimate," "anticipate," "intend," "goal," "strategy," "milestone," and similar expressions and variations thereof. 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, our business strategy, market size, potential growth opportunities 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, 2018. We are providing this information as of the date of this presentation we undertake no obligation 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.

The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

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Financial Highlights

Shares

- 2.7 million common shares (Nasdaq: CHFS)
- Recent price: $2.20 (September 16, 2019)
- Market cap: approximately $6.0 million

Revenue

- 9 consecutive quarters of double-digit growth
- Year 2018 grew 41% vs 2017
- Q2 2019 up 53% from Q2 2018 and 38% from Q1 2019

Liquidity

- Cash on hand $7.4M as of June 30, 2019
- No debt
- 2.3 million warrants callable at $5.25 upon FDA label for pediatrics. Could provide additional $12.4M cash in late 2019

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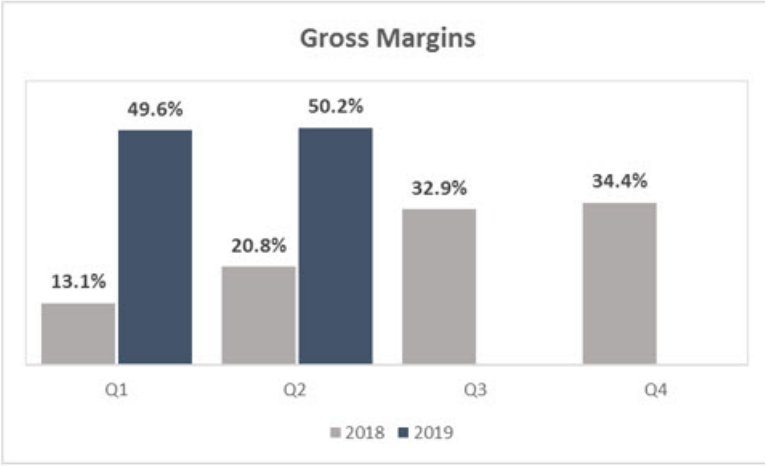
Financial Metrics

Quarterly Revenue, YoY Growth

YoY Growth Rates				
	Q1	Q2	Q3	Q4
2018	15%	27%	42%	80%
2019	17%	58%		

We have delivered double-digit year-over-year quarterly growth for the last 9 quarters

Gross Margins



We began selling our internally manufactured inventory in Q1 2019, driving substantial improvements in our gross margins

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Our Vision

We Are Dedicated To Changing The Lives Of Patients Suffering from Fluid Overload Through Science, Collaboration, And Innovation

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What is Fluid Overload?

- Excess fluid, primarily salt and water, builds up throughout the body resulting in weight gain
- Can result in ER admission, extended ICU stays, preventable death
- Causes include:
  - Heart Failure (HF)[1]
  - Nephrotic Syndrome[1]
  - Liver Damage[1]
  - Kidney Damage[1]
  - Pre- and Post-Cardiothoracic Surgery[2,3,4]
  - Treatment for Burns or Trauma[5]

1. Lewis JL, et al. Volume Overload. Merck Manual (Professional Version). Nov 2016. 2. Holte K, et al. Br J of Anaesth. 2002 Oct; 89 (4) 622-32. 3. Morin JF, et al. World Journal of Cardio Surgery, 2011; 1, 18-23. 4. Pradeep A, et al. HSR Proceedings in Intensive Care and Cardiovascular Anesthesia 2010; 2: 287-296. 5. https://www.renalandurologynews.com/nkf-2012-general-news/fluid-overload-in-burn-patients-affects-survival/article/240978/.

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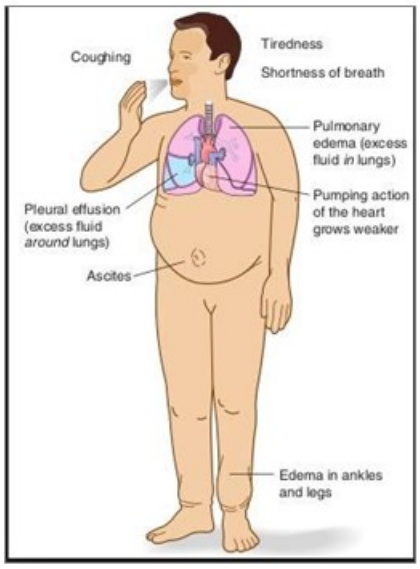
Fluid Overload Causes Significant Complications

- Linked to mortality in critically ill patients[1]
- Associated with dangerous complications, such as[1]:
  - Pulmonary Edema
  - Cardiac Failure
  - Delayed Wound Healing
  - Tissue Breakdown
  - Impaired Bowl Function
- May contribute to renal dysfunction, arrhythmias, and infection[2]



1. Granado R, et al. Fluid Overload in the ICU: Evaluation and Manageement. BMC Nephrology (2016) 17:109 2. Stein A, et al. Critical Care. 2012;16:R99.

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

- 68% show **sub-optimal response,** with 40% exhibiting **diuretic resistance** ("failure")[1]
- Nearly 50% of HF patients are discharged from the hospital with residual excess fluid:[2]
  - Worsening heart failure with **increased mortality** after discharge
  - Insufficient symptom relief, such as **persistent congestion**
  - Increase in **re-hospitalization** rates
  - Risk of **electrolyte imbalances** (i.e. low magnesium and low potassium)

1. Testani, Circ Heart Failure, 2016;9:e002370 2. Costanzo MR, et al., J Am Coll Cardiol., 2017; 69: 2428-45

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Clinical Guidelines Support Use of Ultrafiltration

ACC/AHA – American College of Cardiology/ American Heart Association[1]

HFSA - Heart Failure Society Of America[2]

ESC / HFA - European Society of Cardiology and Heart Failure Association[3]

CCS - Canadian Cardiovascular Society[4]

1 Yancy CW, et al. *J Am Coll Cardiol*. 2013 Oct 15; 62(16): e147-e239.
2 HFSA 2010 Comprehensive Heart Failure Practice Guidelines: Lindenfeld J, et al. J Card Fail. 2010 Jun; 16(6): 475 – 539.
3 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.
4 2012 Canadian Cardiovascular Society Heart Failure Management Guidelines Update: McKelvie RS, et al. Can J Cardiol. 2013 Feb; 29(2): 168 – 181.

Aquadex FlexFlow® System: A Solution to this Unmet Clinical Need

- Safe, effective, and clinically proven to remove excess salt and water from the body
- 40% more fluid removal than conventional diuretic drug therapy over the same period of time[1]
- No clinically significant impact on electrolytes balance, blood pressure, or heart rate[1,2]
- Prescribed by any medical specialty trained in extracorporeal therapy
- 53% reduction in the risk of HF rehospitalization than those treated solely with diuretics at 90 days[3]
- Fewer HF re-hospitalization days due to cardiovascular event[4]

1 Bart BA, et. al., *Am Coll Cardiol*., 2005;46:2043– 6. 2 Jaski BE et al. J Card Fail. 2003; 9(3):227-231. 3 Costanzo MR, et al. *J Am Coll Cardiol*. 2007 Feb 13; 49(6): 675-683. 4. Costanzo MR, et. al., *J Am Coll Cardiol*., 2005;46:2047–51.

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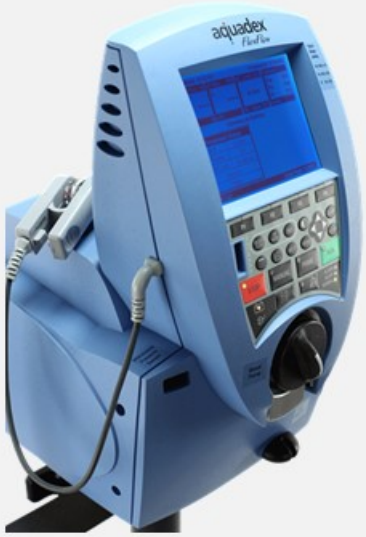
Aquadex FlexFlow Product Overview

Aquadex FlexFlow Console



Blood Circuit Set

Dual Lumen venous catheter

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Aquadex FlexFlow System for Fluid Management

*"Successful fluid overload treatment depends on precise assessment of individual volume status, understanding the principles of **fluid management with ultrafiltration**, and clear treatment goals."*[1]

Target Segments & Addressable Opportunity (US)

Critical Care

- **CV Surgery (VAD, CABG, HV)***
- Liver (Transplant, Disease)
- Dialysis
- Sepsis
- Adult EMCO

**strategic entry point*

$950M

Heart Failure

- Inpatient
- Outpatient

$900M

Pediatric

- Renal Replacement
- Heart Disease
- Cardiac Surgery
- Transplants
- ECMO

$115M

1. Claur-Del Granado R, Mehta M. BMC Nephrology. 2016;109(17):1AB

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Cardiovascular Surgery Market Opportunit

- Over 500,000 US surgeries a year utilize heart-lung bypass machine including:
  - 340,000 coronary artery bypass graft (CABG) procedures[2]
  - 180,000 valve procedures[3]
  - 4,000 ventricular assist device (VAD) implants[4]
- Patients are given fluid to facilitate surgery. 40% of patients cannot eliminate excess fluids post surgery due to Acute Kidney Injury[1]
- Efficient removal can save ICU time and avoid adverse events

1. Ann Thorac Surg. 2011; 92-1539-47). 2. https://idataresearch.com/new-study-shows-approximately-340000-cabg-procedures-per-year-in-the-united-states/. 3. https://idataresearch.com/over-182000-heart-valve-replacements-per-year-in-the-united-states/. 4. https://www.mdedge.com/chestphysician/article/148584/heart-failure/lvad-use-soars-elderly-americans

Heart Failure (HF) Market Opportunity

- Over 6 million people suffer from HF in the US[1]
- 900,000 HF patients are hospitalized each year due to fluid overload[2]
- 68% show sub-optimal or no response to diuretics; 40% are diuretic resistant[3]
- Aquadex FlexFlow can turn a cost center into a profit center

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5494150/. 2. Costanzo MR, et al. J Am Coll Cardiol. 2017;69(19):2428-2445. 3. Testani JM, et al. Circ Heart Failure. 2016;9(1).

Pediatric Market Opportunity

- Addressable market of 40,000[1] patients for both chronic and acute fluid overload conditions, such as heart failure, cardiac surgery, ECMO therapy, transplantation and neonatal kidney replacement.
- Includes 11,000[1] neonates born each year with compromised kidneys and a 50% mortality rate. No alternative solutions for premature babies.
- Historically an underserved market
- Expect FDA label expansion in pediatrics late Q4 2019

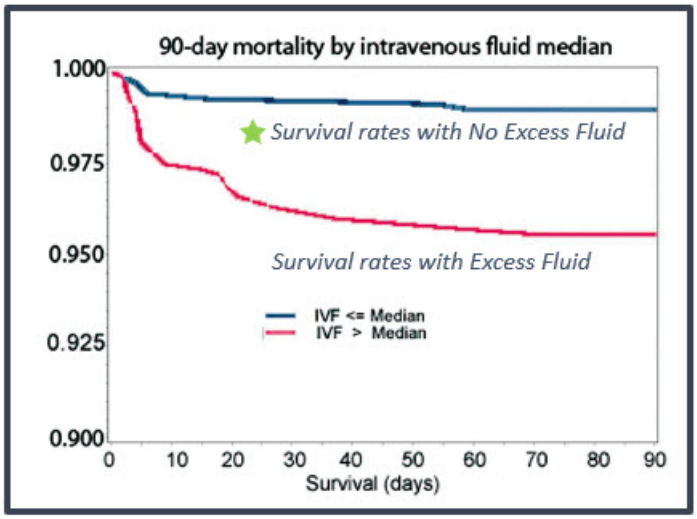
1. See slide 23 for references.

Acute Need in Cardiac Surgery: Fluid Overload is Associated with Greater Mortality

CV Surgery

Fluid Overload is Associated with 300% Increase in 90 Day Mortality Rates Post CV Surgery

- Retrospective analysis on 1,358 patients who underwent cardiac surgery
- Greater amount of IV fluid during cardiac surgery associated with *three-fold increase* is mortality at 90 days



Source: Pradeep, A. et al. HSR Proc IC and Car An. 2010 Mar; 2(4): 287-296

Aquadex FlexFlow Provides Significant Clinical and Economic Benefits in CV Surgery

CV Surgery

- Modified ultrafiltration reduces duration of assisted ventilation post cardiac surgery[1,2,3]
- Aquadex FlexFlow not considered renal replacement therapy from a quality reporting standpoint
- No Nephrology consultation required to prescribe Aquadex FlexFlow

1.Luciani GB, et al. Circulation. 2001 Sep 18;104(12 Suppl 1): I253-I259. 2. Kiziltepe, U, et al. Ann Thorac Surg. 2001 Feb;71(2): 684-93. 3. Grunenfelder et al. Eur J of Cardio-Thoracic surgery.2000; 17:77-83.

Most US Hospitals Lose Money on a Heart Failure Admission

- There is great concern throughout the US healthcare system regarding the high and growing economic burden for treating heart failure.
- Heart failure treatment is Medicare's largest expenditure.
- Most US hospitals lose money on a heart failure admission – the average length of stay is 6-days, while DRG payments only cover up to 4-days.
- Diuretics are the current standard of care.
- Hospital administrations are actively pursuing projects and processes to reduce the growing economic burden of heart failure.

HF Costs to US Healthcare System[1]

$30.7 Billion

in health care services, medications to treat heart failure, & missed days of work

1. Heidenreich PA, Trogdon JG, Khavjou OA, Butler J, Dracup K, Ezekowitz MD, et al. Forecasting the future of cardiovascular disease in the United States: a policy statement from the American Heart AssociationExternal. *Circulation*. 2011;123(8):933–44.
2. Costanzo MR, et al. J Am Coll Cardiol. 2017;69(19)2428-2445

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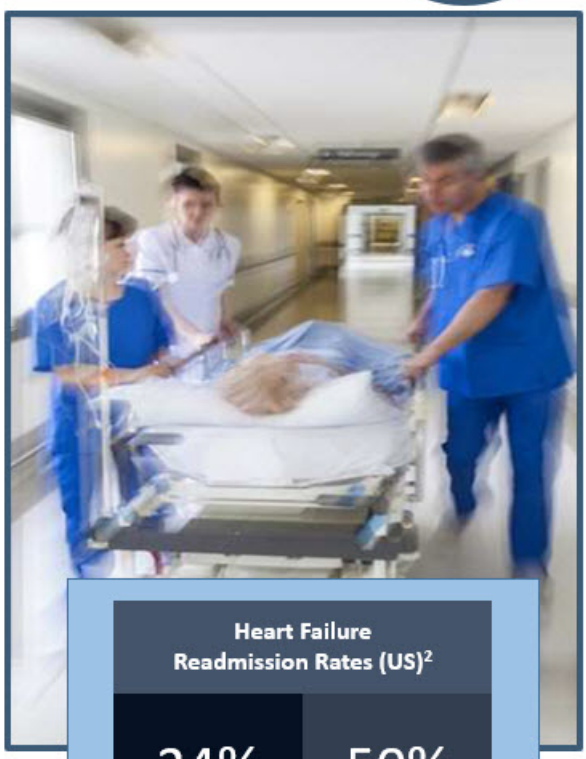
Medicare Penalizes Hospitals with Excessive HF Readmissions

In 2012, the Affordable Care Act instituted the Hospital Readmission Reduction Program[1]

- **Statistics:** CMS shows 25% of heart failure patients are readmitted to the hospital within 30-days
- **Requirement**: CMS to reduce payments to hospitals with excess 30-day readmissions
- **Penalty #1:** No additional DRG payment for patients readmitted to the hospital within 30-days of initial discharge
- **Penalty #2**: hospitals can lose ≤3% of Medicare reimbursement on **all** admissions



Heart Failure Readmission Rates (US)[2]

24%	50%
within 30 days	within 6 months

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

Economic Benefits of Using Aquadex FlexFlow in the Inpatient Heart Failure Setting

- Ultrafiltration has shown significant decreases in heart failure ***rehospitalizations and rehospitalization lengths of stay*** compared to diuretics[1]
- Recent analysis demonstrated a cost savings of ***$3,975 per patient*** when using ultrafiltration versus diuretic therapy over 90 days[2]
- An Aquadex FlexFlow program reduces excess readmissions and reduces Medicare DRG penalties

Ultrafiltration vs. Diuretics for the Treatment of Fluid Overload in Patients with Heart Failure: A Hospital Cost Analysis

Background

Objective

Methods

Figure 1: Decision Analytic Framework*

Results

Figure 2: Hospital Readmission Costs per Patient at 90 Days following Discharge

Figure 3: Tornado Diagram for One-way Sensitivity Analysis

Conclusion

1. Costanzo MR et al. J Am Coll Cardiol. 2007;49(6):675-683. 2. Costanzo MR, et al. Ultrafiltration vs. Diuretics for the Treatment of Fluid Overload in Patients with Heart Failure: A Hospital Cost Analysis. Value Health.

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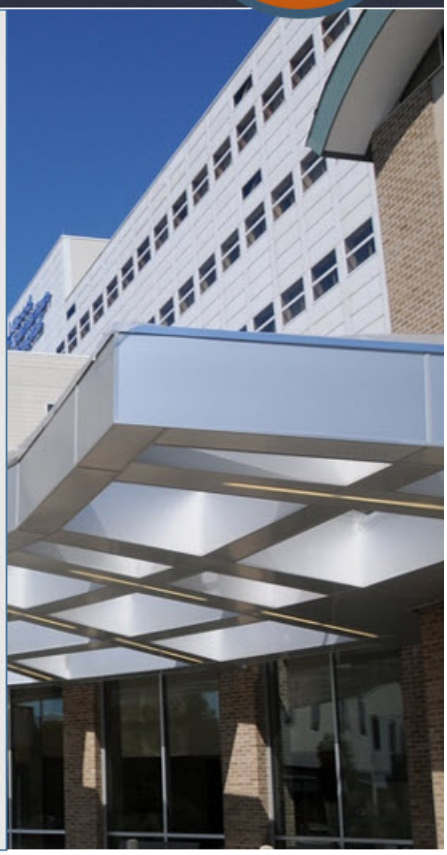
Clinical Results Demonstrate the Potential of Aquadex FlexFlow

Good Samaritan Hospital-A Single Center Experience

Independent study of 67 heart failure patients who received Aquadex FlexFlow therapy:

- 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.



Significant Opportunity in Heart Failure For Outpatient Setting

VA/Department Of Defense Opportunity

- Goal of VA/DOD health systems is to avoid HF hospital admissions
- Tampa VA conducting clinical study on outpatient use of Aquadex FlexFlow
  - Q3/Q4 2019 initiation
- $6.5M blanket purchase agreement received for outpatient trial at Tampa VA

Hospital and Health System Opportunity

- Goal is to manage HF patients proactively to avoid 30-day readmissions
- 2 hospitals currently offering Aquadex FlexFlow therapy in an outpatient setting:
  - Christ Hospital in Cincinnati
  - Medstar Good Samaritan in Baltimore

James Haley Veterans' Hospital and Clinics Tampa

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Pediatrics: Providing a Solution in an Underserved Market

Aquadex FlexFlow/ultrafiltration is currently being prescribed by physicians to treat various pediatric conditions:

Acute

- Kidney replacement therapy (11,000 patients/yr) [1]
- Cardiac surgery (10,000 procedures/yr) [2]
- Extracorporeal membrane oxygenation (ECMO) therapy (6,000 procedures/yr) [3]
- Solid organ transplantation (2,000 procedures/yr) [4]

Chronic

- Heart Disease (12,000 patients/yr) [5]

Q3 2019 510(k) filing with FDA for Pediatric indication

- Label expansion for pediatrics >20kg expected approximately 90 days post submission

1. https://www.ncbi.nlm.nih.gov/pubmed/23833312
2. https://www.cdc.gov/ncbddd/heartdefects/data.html
3. https://www.ncbi.nlm.nih.gov/pubmed/23246046.
4. https://www.organdonor.gov/about/donors/child-infant.html.
5. http://www.heartviews.org/article.asp?issn=1995-705X;year=2016;volume=17;issue=3;spage=92;epage=99;aulast=Jayaprasa

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We Are Evaluating New Predictive Diagnostic Tools

- Physicians need new diagnostic tools to better manage fluid overload to:
  - Assess which patients are best candidates for ultrafiltration
  - Target how much fluid to remove
  - Know when the patient is approaching dry weight and to discontinue ultrafiltration
- We are evaluating diagnostic technology internally and with partners:

Daxor Corporation: (NYSE: DXR) Daxor is providing clinically-proven blood volume analysis

NIMedical, Inc.: NIMedical has developed new capabilities in using bio-impedence to assess fluid levels in humans

AcQtrac System, acquired in mid-2018: designed to noninvasively provide real-time measurements of hemodynamic parameters in fluid overload

Expanding Commercial Distribution

- US direct sales team growing to 15 sales territories and 15 clinical education specialists
- Distribution partners in UK, Italy, Germany, Spain, Singapore, Hong Kong, Thailand, India and Brazil
- FDA 510(k) market cleared in US; sold internationally with local regulatory approval
- Manufacturing all products in our Minneapolis, MN facility

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CHF Growth Metrics

- 270 Aquadex FlexFlow systems installed in 125 hospitals
- Optimal utilization is 100 disposables per year per system
- Current utilization is 16 percent
- Cardiac hospital penetration <2 percent
- Addressable US market segments total >$2.0 billion annually
- Additional opportunities beyond current markets include intensive care unit (ICU) settings such as burn, trauma and sepsis
- Worldwide opportunity is 3x US market size

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CHF Solutions Investment Considerations

- **Rapidly growing, revenue generating, medical device company**
- **Expanding commercial focus beyond initial market**:
  - **Heart Failure**: our largest market opportunity, pursing diagnostic opportunities to expand adoption. Increasing focus in outpatient hospital clinics and leveraging Tampa VA outpatient clinical study
  - **Cardiac Surgery:** leveraging acute need and clinical and economic benefits to drive adoption
  - **Pediatrics:** providing a solution to an underserved market and seeking label modification
- **US commercial footprint and growing international distributor network**
  - U.S-based direct sales force and clinical education support specialists
  - Growing international distribution network
- **Anticipated milestones**
  - Tampa VA first patient enrollment in outpatient study – Q4 2019
  - Pediatric label expansion: Q4 2019
  - Therapy initiation in several hospital systems for CV Surgery and Heart Failure

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Thank you