at a glance™

chf solutions

***Of Note:** CHF Solutions revenue for 2Q19 was $1.7 million, up 53 percent from the year-ago quarter and 38 percent from 1Q19, making it the ninth consecutive quarter of double-digit revenue growth. Margins grew to 50 percent from 21 percent a year-ago. The number of field education specialists has increased from five to 14 as new marketing strategies take the company into acute care markets with shorter sales cycles. Seven new hospitals were opened in 2Q19, with 10 more new accounts on deck to open in 3Q19, including two hospital systems that operate 39 hospitals. An FDA 510(k) market clearance, anticipated by year-end, will allow the company to expand into the pediatrics market where its technology is currently being used to treat a life-threatening birth defect in premature babies, potentially saving hundreds of neonatal lives.*

Key Considerations

- **CHF Solutions makes state-of-the-art hospital-based systems for removing excess fluids (primarily salt and water), currently from heart failure patients and cardiac surgery patients recovering in the ICU.**
- **In the US alone, it's estimated that 1.4 million adult patients each year require hospitalized treatment for removal of excess fluids. The pediatric market adds another 40,000 patients.**
- **In the past, the principal way to treat fluid overload was with conventional diuretic drugs. They're designed to make patients urinate as the way to rid the body of excess fluids. But 68 percent of patients experience suboptimal response to diuretics, including 40 percent who fail to respond at all to the diuretics.**
- **CFS solves the problems of diuretics with its patented Aquadex FlexFlow® system which separates excess water and salt from the blood, then returns the filtered blood into circulation.**
- **The addressable markets of heart failure, cardiac surgeries and pediatric interventions are large.**
- **Six million in the US have chronic heart failure and account for one million hospital admissions each year, 90 percent due to fluid overload.**
- **Half a million cardiac surgeries are performed each year in the US utilizing a heart-lung machine. Forty percent of these patients are candidates for Aquadex FlexFlow therapy.**
- **Over 40,000 pediatric patients require ultrafiltration for life-saving therapies, including cardiac surgery, treatment of heart failure, extracorporeal membrane oxygenation (ECMO), solid organ transplantation, and kidney replacement therapy.**
- **A 510(k) application to expand FDA market clearance of Aquadex FlexFlow for pediatrics is expected to be filed in 3Q19.**
- **In addition to systems sales, CHFS captures recurring revenue from the sale of single-use disposables required for each Aquadex FlexFlow treatment session.**
- **Expansion overseas is underway through specialized distributors. Nine countries are currently covered, the two newest being India and Brazil.**
- **Revenue for 2Q19 was $1.7 million, up 53 percent from the year-ago period, and 38 percent from 1Q19. Margins are now 50 percent, roughly 2.5 times higher than last year's average. 2018's $5 million in revenue beat the previous year's by 40 percent. Cash at June 30, 2019 stood at $7.4 million.**

CHF Solutions, Inc.
(Nasdaq: CHFS)

Recent Price: $2.05
Shares O/S: 2.5 Million
Approx. Mkt Cap: $5.1 Million
Cash at 6/30/19: $7.4 Million

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Overview

Aquadex FlexFlow's success in improving the efficiency and economics of fluid removal in chronic heart failure patients has set the stage for a transformative move into two acute care markets, cardiac surgery and neonatal kidney failure.

Cardiac surgeons and pediatric nephrologists face the same challenge of excess fluid removal as heart failure doctors, but their adoption of Aquadex FlexFlow is proving to be much more rapid and unencumbered by the vagaries of Medicare reimbursement.

Roughly 40 percent of the half million "on pump" heart surgeries in this country each year require removal of excess fluids before the patients leave the ICU. Rapid removal not only saves ICU costs, but also lessens the chance of death within 90 days.

The need in neonatal kidney failure is even more acute. Eleven thousand premature babies are born each year with malfunctioning kidneys. They can't urinate. Some have kidneys that will begin to function naturally with time. Others will go on to have kidney transplants. Still others will be treated with patched together systems. With all that, 50 percent will not survive.

The Aquadex FlexFlow system, currently being used at six of the nation's top children's hospitals, is proving to be well suited to draw fluids from babies whose birthweights are 5.5 pounds or less. The amount of blood needed to operate the pumps (33 ml) is within the amount that can be drawn from preemies without affecting blood pressure and chemistry, two extremely critical parameters.

The Aquadex FlexFlow

Unlike diuretics, Aquadex FlexFlow

Notable & Upcoming

500,000 – heart surgery patients with excess fluids

900,000 – heart failure patients with excess fluids

40,000 – pediatrics with fluids overload, including 11,000 neonates

$1.4 – billion addressable market for Aquadex FlexFlow consumables

3Q19 – Filing of 510(k) for pediatric procedures

3Q19 – First patient in Tampa VA outpatient study

4Q19 – Anticipated 510(k) market clearance for pediatrics

doesn't rely on the body's biological functioning. It's programmable, predictable, and it doesn't impact electrolytes, blood pressure or heart rate.

Aquadex FlexFlow removes 40 percent more fluids in the same time as diuretics. It consists of a portable console with two peristaltic pumps attached to a single-use catheter-filter assembly that separates excess water from the blood, then returns the filtered blood into circulation.

The console lists for $39K. Each single-use catheter-filter set sells for $980.

Chronic Heart Failure

Heart failure accounted for just under half of CHFS's 2018 revenue. It's a bedrock market for CHFS and it's been instrumental in demonstrating how Aquadex FlexFlow's efficacy and economics can benefit additional patient populations.

Failure to remove excess fluids from chronic heart failure patients can lead to breathing distress, ER admissions, multiple comorbidities, and death in the critically ill.

Diuretics, the stand-by therapy, don't always work, and when they do, they often work slowly. Sixty eight percent of patients have a less than ideal response to diuretics, including forty percent that don't respond at all.

Aquadex FlexFlow, on the other hand, is predictable, safe and effective.

It speeds the removal of fluids and provides a way for hospitals to save thousands of dollars by lowering heart failure readmissions and avoid potential Medicare reimbursement penalties of up to 3 percent of all reimbursements – a withering punishment for inadequate care.

Studies show Aquadex FlexFlow takes an average of 3.2 days to remove excess fluids, keeping the hospital stay within the four-day DRG reimbursement limit. Patients on diuretics typically stay for six days, two of which -- at a cost of roughly $1500/day -- are not reimbursed.

The reduction in hospital time and fewer readmissions enable Aquadex FlexFlow to produce an overall cost savings per patient of $3,975 over 90 days, even when taking into account the initial cost of the console, according to a study reported in the *Journal of Medical Economics*.

More rapid adoption of Aquadex FlexFlow for heart failure is anticipated as new reimbursement codes kick in and Medicare begins paying for routine outpatient fluid removal, just as it does for many other chronically needed procedures, like kidney dialysis.

Industry observers predict the emergence of facilities exclusively devoted to fluid removal. The Tampa VA has received authorization for $6.5M to initiate a study to treat veterans suffering from fluid overload on an outpatient basis utilizing Aquadex FlexFlow. First patient is expected to enroll in 3Q19.

Cardiac Surgery

Heart surgeries are performed on about seven million people in the US each year. Roughly half million of these surgeries are on a heart-lung machine where patients are administered fluids to facilitate the surgery. Forty percent of patients suffer from acute kidney injury post-surgery and are candidates for Aquadex FlexFlow to aid in the removal of excess fluids. This represents roughly $200 million of the $1.4 billion addressable market for Aquadex FlexFlow consumables.

Leading cardiac surgery centers, including Mt. Sinai in New York City, currently with eight Aquadex FlexFlow systems, have become early adopters.

Excess fluids buildup in cardiac surgery patients begins as soon as they're hooked up to heart-lung bypass apparatus prior to coronary bypass (CABG), left ventricle pump implants (LVAD), and similar procedures.

Doctors infuse roughly four to six liters of fluid into the patient to replace the volume of blood that's pumped out of the body to fill the fluids processing chamber of the heart-lung machine.

At the end of surgery, the patient is left with 8 to 15 pounds of extra fluid (water+salt) that must be substantially drawn off before leaving the ICU.

Getting patients back to dry weight with normal heart volume, heart rhythm and blood pressure is a prime objective.

The faster this is done the better. Multiple studies show the longer a patient stays in the ICU, the higher the mortality.

A retrospective study of 1,358 patients who underwent cardiac surgery showed excess fluid led to a three-fold increase in mortality at 90 days post procedure.

The two main fluid removal goals are: (1) best practice care while reducing ICU time; and (2) avoiding the need for a nephrology consult and the mandatory sequela, the posting of an adverse event.

If diuretics fail, the surgeon's only option until recently has been to call for a nephrology consult and the use of a special fluid processing machine which can be operated only by a nephrologist.

That decision triggers the public posting of an adverse event, potentially affecting referrals to the hospital/doctor and ultimately reimbursements.

Surgeons can now avoid the nephrology consult by using Aquadex FlexFlow. Any healthcare professional with training in extracorporeal (outside the body) therapies can administer the treatment under the prescription of a physician who's been similarly trained.

Pediatrics

Aquadex FlexFlow holds the potential of helping over 40,000 pediatric patients, once its approved for use in pediatric patients (defined by the FDA as under 20 years of age).

The approval, which is anticipated by year-end, is expected to clear the way for treatment of pediatric use in many clinical conditions, including heart failure, cardiac surgery, extracorporeal membrane oxygenation (ECMO) therapy, solid organ transplantation, and kidney replacement therapy for neonatal patients.

It is estimated that there are approximately 10,000 to14,000 pediatric patients with heart failure, approximately 18,000 receiving cardiac surgery, ECMO therapy, and solid organ transplantation and approximately 11,000 premature babies born each year with failed or compromised kidneys.

Neonatal patients with compromised kidneys can't naturally off-load urine. Fluid overload rapidly sets in, putting them in a potentially life-threatening situation. Less than 50 percent currently survive.

A study of Aquadex FlexFlow in neonatal kidney failure at three of the nation's highly respected children's hospitals is expected to be published later this year.

Summary

- **CHFS's strong footing in the chronic heart failure market is now being leveraged in two new markets – both acute care – where there's significant opportunity of more rapid growth and quicker adoption – a key to increasing the sales of Aquadex FlexFlow single-use disposables.**
- **In cardiac surgery there is an acute need to bring patients back to dry weight as soon as possible in the ICU – diuretics often don't do the job, whereas Aquadex FlexFlow is predictable. This can shorten expensive stays in the ICU and avoid adverse events.**
- **In neonatal kidney failure, an application that is subject to FDA clearance, Aquadex FlexFlow holds the hope of helping save hundreds of babies born prematurely with failed or malfunctioning kidneys. Of the 11,000 born each year, half currently die due to inadequate treatment options.**
- **The chronic care heart failure segment continues to represent the largest market opportunity and is predicted to remain strong, but it will represent a declining share of total revenue, at least for the next few years while the company prioritizes new market opportunities in acute care settings.**
- **Look for continuing quarterly revenue gains, building on nine consecutive quarters of sales growth, and an important FDA market clearance (pediatrics) by year end.**

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