**Spectral Medical Inc.** AGM Presentation June 3, 2021





### Forward Looking Statements



Certain statements contained in this presentation constitute forward-looking information within the meaning of securities laws. Forward-looking information may relate to our future outlook and anticipated events or results and may include statements regarding our future financial position, business strategy, budgets, litigation, projected costs, capital expenditures, financial results, taxes and plans and objectives. In some cases, forward-looking information can be identified by terms such as "may", "will", "should", "expect", "plan", "anticipate", "believe", "intend", "estimate", "predict", "potential", "continue" or other similar expressions concerning matters that are not historical facts. These statements are based on certain factors and assumptions regarding, among other things, expected growth, results of operations, performance, and business prospects and opportunities. While we consider these assumptions to be reasonable based on information currently available to us, they may prove to be incorrect. Forward looking-information is also subject to certain factors, including risks and uncertainties that could cause actual results to differ materially from what we currently expect. These factors include, among other things, the availability of funds and resources to pursue development projects, the successful and timely completion of clinical studies, and the ability to take advantage of business opportunities, the granting of necessary approvals by regulatory authorities, and general economic, market and business conditions. For more exhaustive information on these risks and uncertainties you should refer to our most recently filed Annual Information Form which is available at www.sedar.com. Forward-looking information contained in this presentation is based on our current estimates, expectations and projections, which we believe are reasonable as of the current date. You should not place undue importance on forward-looking information and should not rely upon this information as of any other date. While

### Agenda

- Fiscal 2020 Year in Review
- 2021 Outlook
- Tigris Trial Update
- Dialco Update
- Closing Remarks
- Q&A





# TIGRIS – Update

Presented by Dr. John Kellum

# **Tigris Reboot**



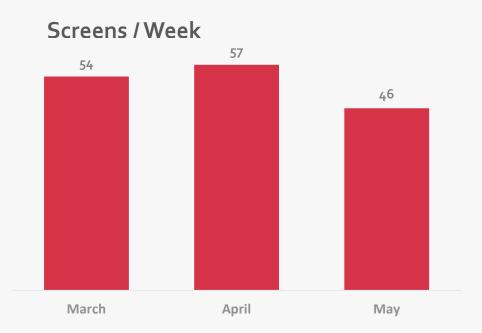


**Current Tigris Status** 

# Patients Randomized: 15

# Prescreen / week: 46-57

# • Open to enrollment: 11 sites





## COVID-19 Impact on Sepsis Research



Impact at multiple levels

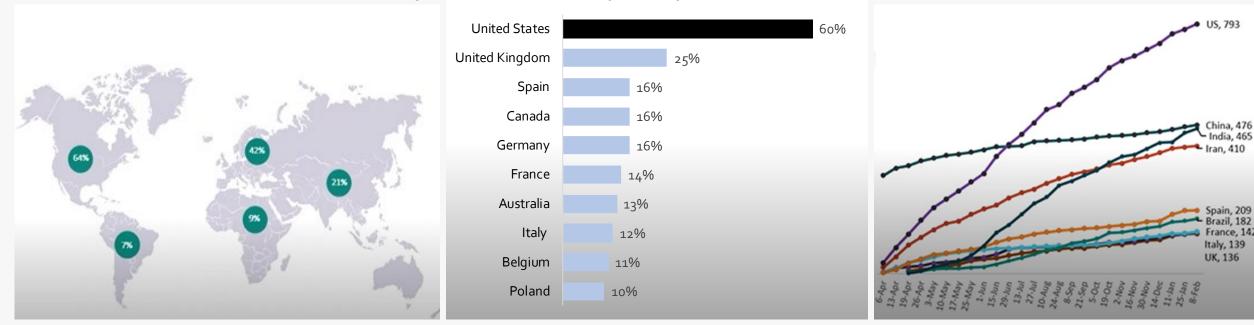
- Prioritization of COVID-19 studies
- Restrictions placed on research activities
- Fewer cases of bacterial sepsis
- Reduced availability of research personnel

   Research personnel redeployed in the clinical enterprise
   Dialysis nurse shortages
   Burnout



### Worldwide Disruption of Clinical Trials Due to COVID-19

Percent of Clinical Trials Disrupted Due to COVID-19 by Country



Source: GlobalData Pharmaceutical Intelligence Center, Accessed 8 February 2021



Countries with More Than 125 COVID-19 Trials





# Reboot Plans: New Sites, Carrots and Sticks

• New sites

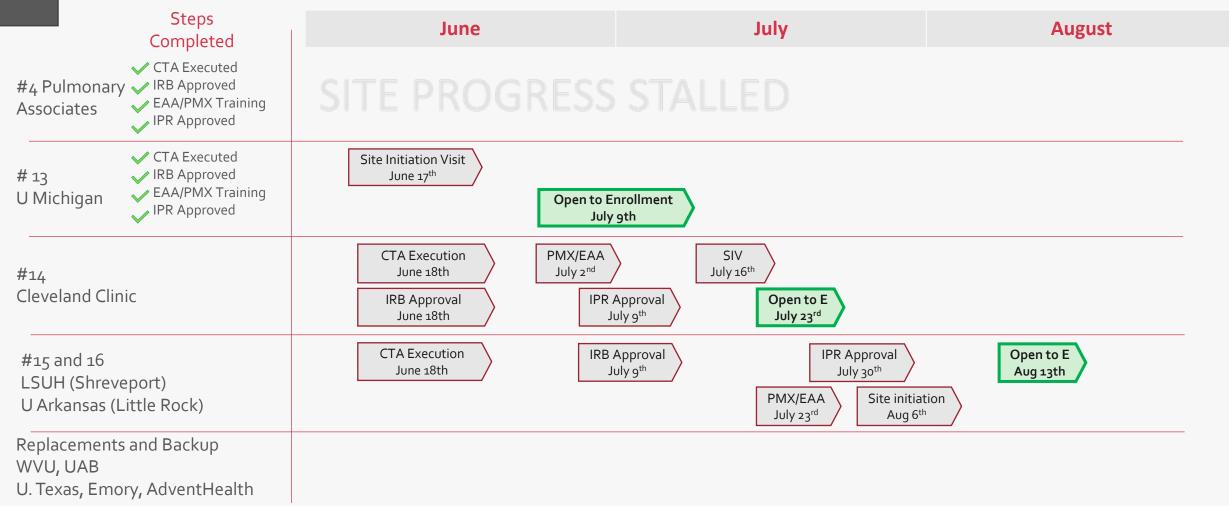
Adding 2 new sites immediately (U Michigan, Cleveland Clinic)
 2 more close behind (U Arkansas, LSU Shreveport)
 Others being considered

- Sticks
  - $\circ$  Site probation
  - Possibly replace 3-4 sites in coming months
- Carrots

Sub-studies for new products (SAMI, Prismax with HP)



# **New Site Timeline Projections**





# Tigris Investigator Meeting, June 11

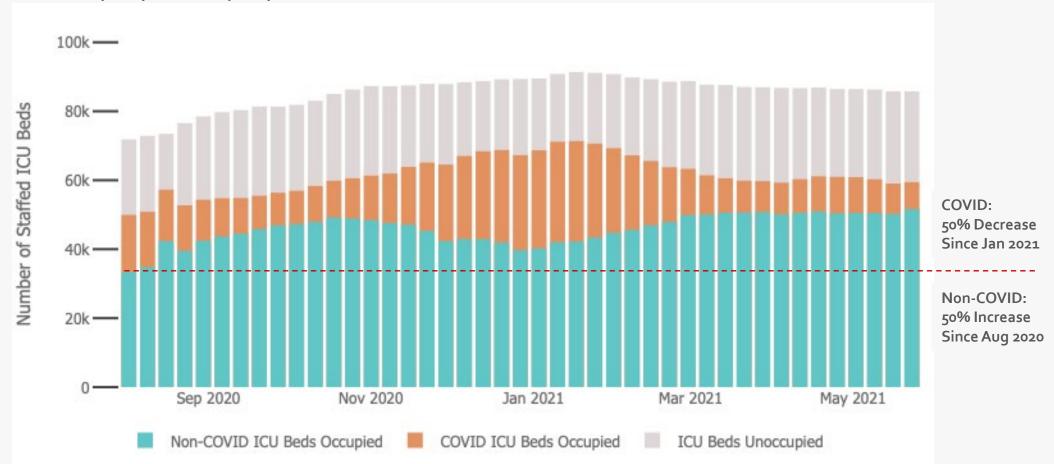
	Time	Topic	Speaker				
TIGRIS	1000-1015	Welcome and Introductions	Debra Foster				
INVESTIGATOR MEETING	1015-1045	Hemoperfusion has a place in critical care	Rinaldo Bellomo				
	1045-1130	EDEN project: The landscape between two great Rivers	John Kellum				
VIRTUALLY, FROM THE		MODS vs SOFA - what's new for Tigris?	Debra Foster				
LAND DOWN UNDER	1130-1200	Break					
JUNE 11, 2021	1200-1230	Let's Play Jeopardy!	Guest Host: Debra Foster				
	1230-1300	Regulatory roundup: a primer on CAPAs and root cause analysis	Danijela Domljanovic				
AGENDA	1300-1330	Bayesian analysis in this SAP	George Tomlinson				
Tieris	1330-1400	Hot off the press for PMX	Gualtiero Guadagni				
	1400-1430	Session A: Applying MODS/SOFA Session B: Tigris Advisory Committee	Breakout sessions				
1 million							





# **Non-COVID ICU Patients Now Surging**

US ICU Capacity and Occupancy





### Enrollment Rate To-Date Not Optimal... However, the 'Unaffected' Enrollment Rate in Tigris Robust

	e	1	2	3	5	6	7	8	9	10	11	TOTAL
Ope	en to Enrollment	17-Oct-19	18-Oct-19	08-Nov-19	26-Feb-20	29-Jan-20	20-Feb-20	21-Jan-20	28-Feb-20	03-Nov-20	09-Nov-20	
# M	Nonths of Enrollment	10	10	10	7	8	11	12	7	3	3	81
Current # Ra	Randomized	2	0	1	0	1	6	4	0	0	1	15
	cruitment Rate	0.20	0.00	0.10	0.00	0.13	0.55	0.33	0.00	0.00	0.33	0.19

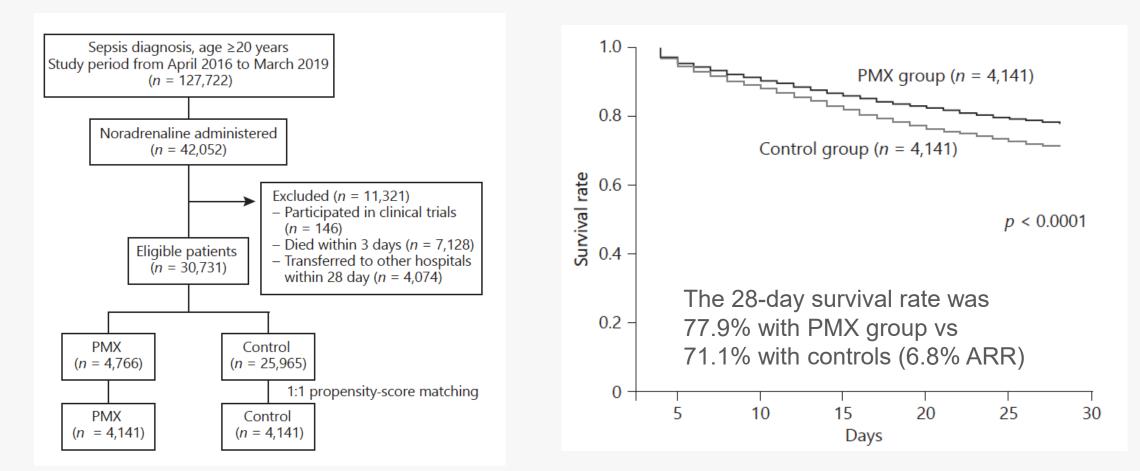
All sites (except #7 & #8) discounted for recruitment suspension Mar-Jul

With an alternate forecast where non-enrolling sites are removed and actual screening time per site is calculated:

15 patients /6 sites/ 30 months = recruitment rate 0.83



# Survival benefit with PMX-hemoperfusion... New Real World Data





Fujimori, et al. Blood Purif. 2021 Feb 12;1-6.

# Conclusions

- Outlook for sepsis clinical research still guarded but COVID impact diminishing and non-COVID cases increasing
- Site activity is increasing and new sites are coming on board
- Trial "reboot" activities are underway
- New data from Japan continues to support a robust effect for PMX



# **Dialco Medical – Update**

Presented by Dr. Gualtiero Guadagni



### YOUR NEW PARTNER in DIALYSIS

### Dialco Strategic Priorities 2021 – 2022

#### **Commercialization**

- US and Canada field staff recruitment and expansion
- Increase Dialco footprint in US and Canadian markets
- Leverage current customer experience

#### **Operation**

- Product portfolio completion (PD extension, dialysate and other ancillaries)
- Logistic enhancement and optimization

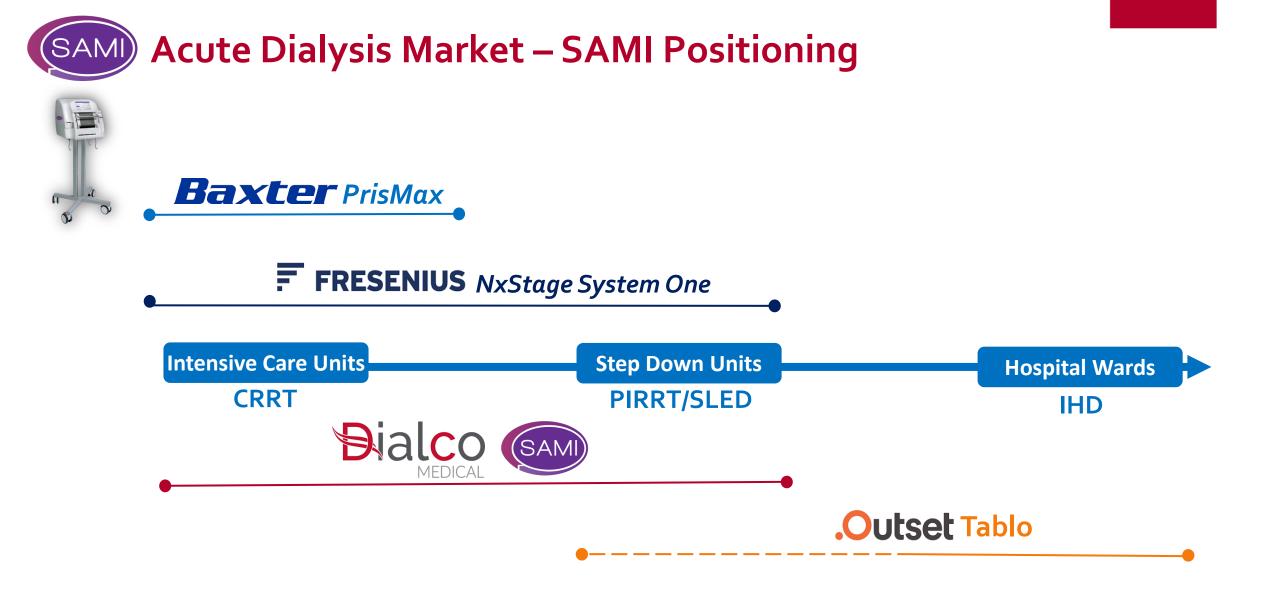
#### **DIMI IDE Usability Trial**

- Engage CRO and contract clinical sites in Q2 2021
- Start site activation in Q<sub>3</sub> 2021
- Enrol first patient in September 2021
- Study completion in September 2022



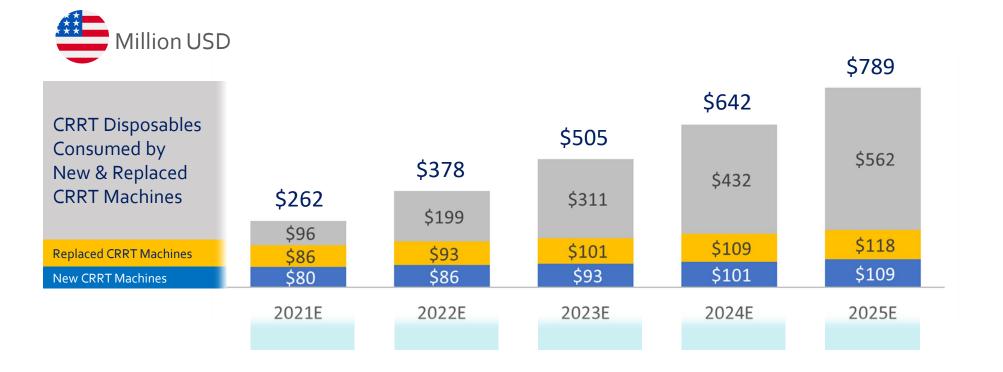












1. Dialco Management estimates as of June 2021, by market growth of 7% and annual replacement of old machines, and disposables consumed by the number of machines



# SAMD Virtual Training, Deployment & Clinical Support



#### **SAMI Virtual Training Program**

Dialco team providing virtual training to University of Michigan team





24/7 Virtual Clinical Support Dialco clinical staff available 24/7 to provide support



#### SAMI CRRT System in Action

The SAMI System deployed shortly after virtual training







Users Prefer SAMI over Traditional CRRT Machines Surveyed 10 nurses trained remotely 1

Training and Learning

Setup

**Trouble Shooting** 

**Graphical User Interface** 

Flexibility



"The disposable cassette is very easy to assemble, you just plug and play."<sup>2</sup>

"Nurses were successfully trained through only one-time virtual training provided by Dialco, which I don't think any other machines can achieve the same outcome."<sup>2</sup>

"It is easy to use, safe and effective. We have great results with SAMI in the use of CRRT and PIRRT. You are able to deliver whatever the patient needs through solid control, which is ideal in the crisis situation."<sup>2</sup>

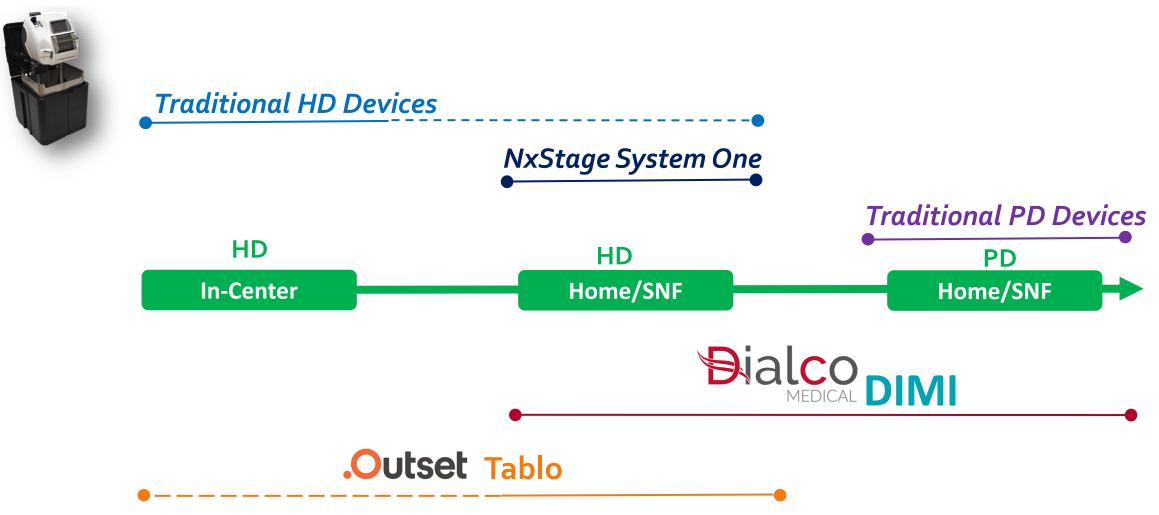
"We have no safety concerns whatsoever recorded."<sup>2</sup>

1. Modified based on research result published in the Journal of Blood Purification - Deployment of New CRRT/PIRRT Device during the COVID-19 Pandemic Emergency: Organizational Challenges and Implementation Results

2. Source: User interviews

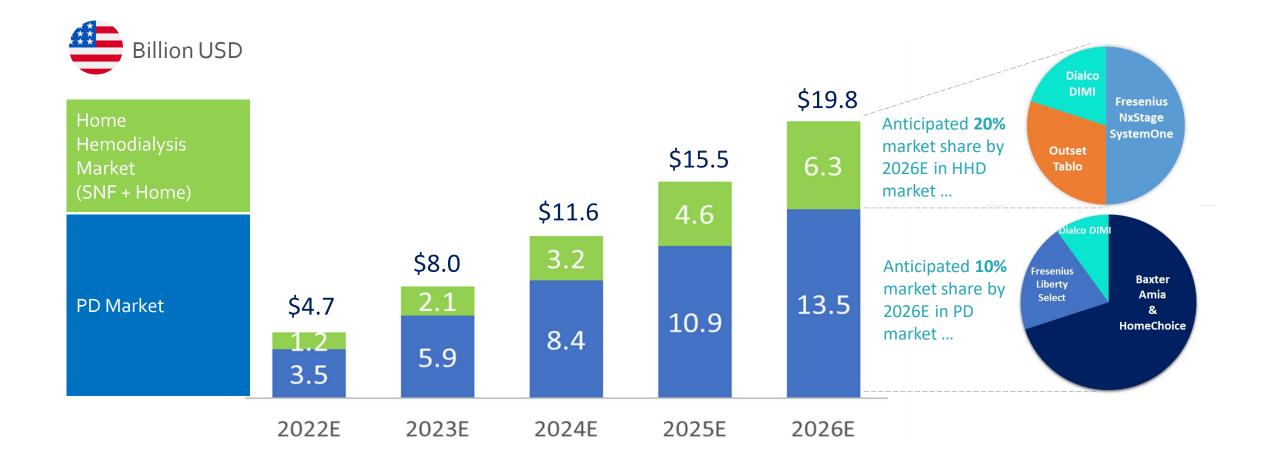


### **D** Chronic Dialysis Market – DIMI Positioning





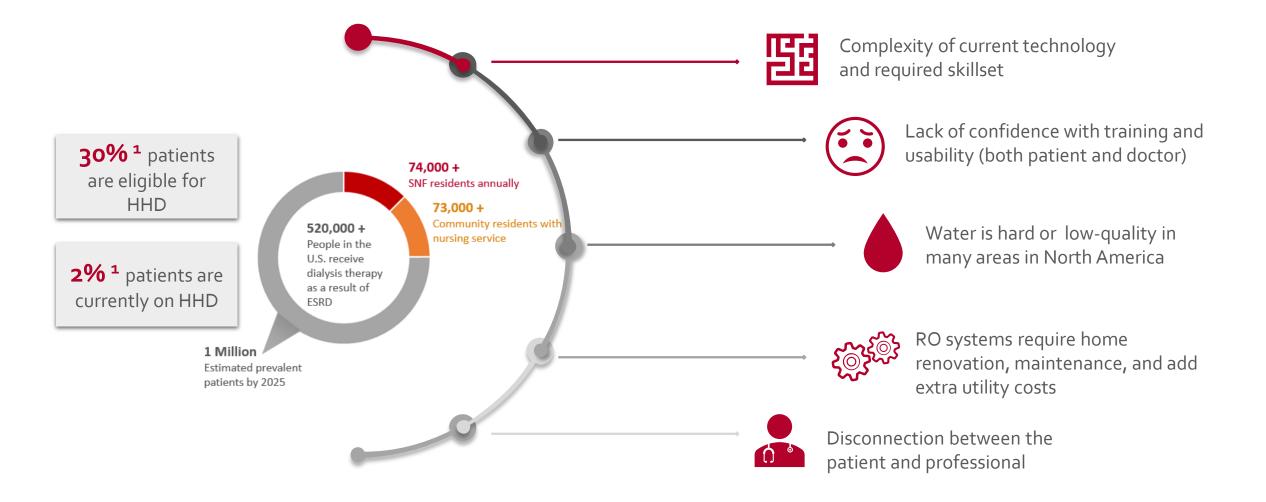
### **D** Total Addressable Market 2021- 2025 <sup>1</sup>



1. Dialco Management estimates as of May 2021, including market size of machines and disposables



### **DIMI** Addresses Barriers to Home Adoption



#### 1. Dialco Management estimates as of May 2021



### **DIMI** Patient Experience <sup>1</sup>

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T	M	M

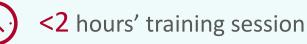
**10** novice and experienced users (5/5) from various social categories



53 years old on average (34 ~ 83 years)



60% vs 40% female and male



All users passed the in-vitro test independently and successfully from their first time

#### "DIMI is extremely instinctive and playful"

#### "The pictogram clearly helps to understand and use"

"The information, alarm signals and messages do not generate stress"



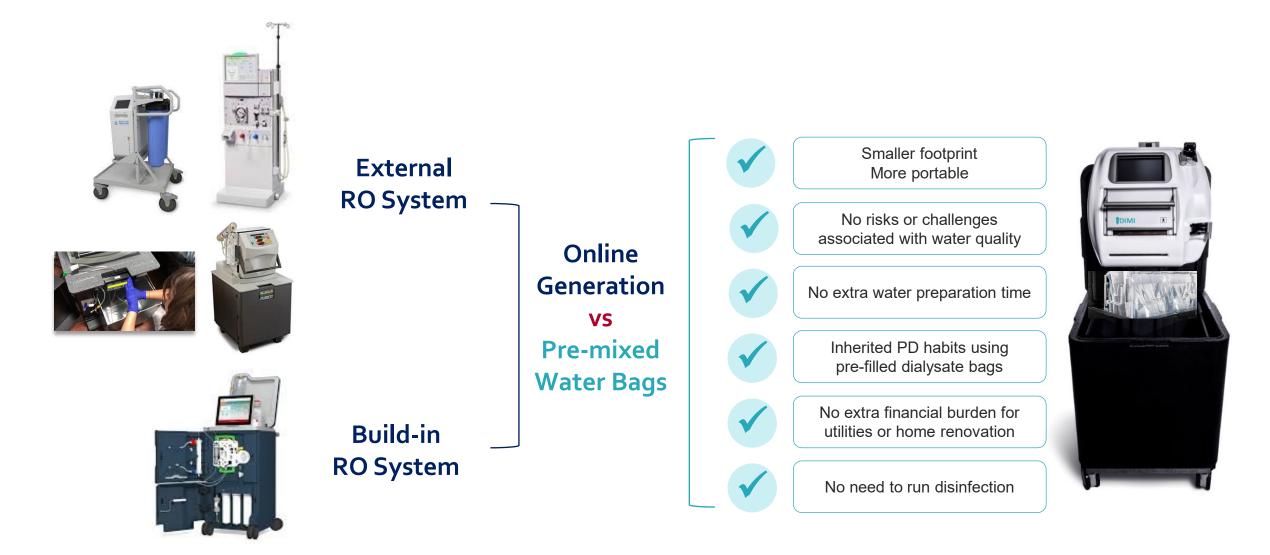
"Solo treatment is totally possible with DIMI"

> "DIMI is so small and silent for home"



1. Human Factor Engineering Report conducted by Dialco

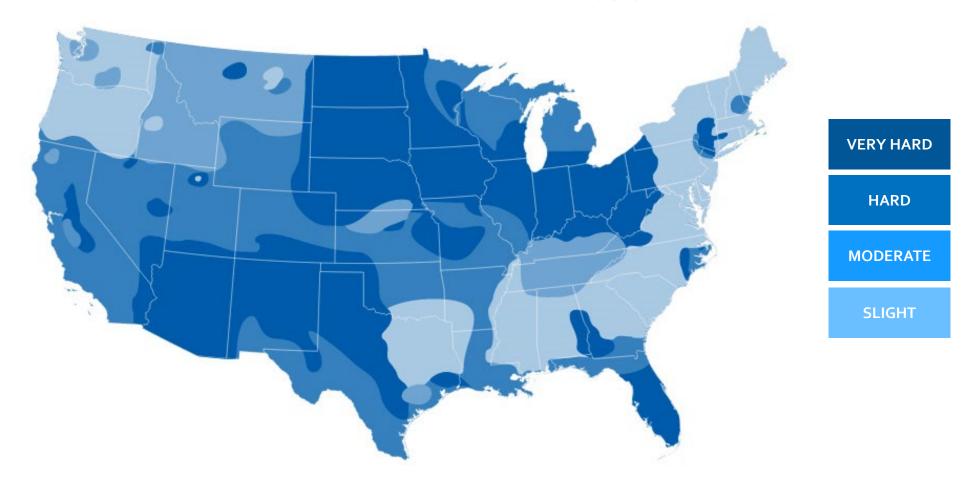
### **Dialysate – Online Generation or Pre-Mixed?**





### **Dialysate – Online Generation or Pre-Mixed?**

Water hardness effects over 85% of the water supply in US 1...



1. Dialco Management estimates based on a study from the National Water-Quality Assessment Project



### **Consumables Storage – Online Generation or Pre-Mixed?**

#### **Dialysate Choice**



#### **Consumables Requirements**



5L Pre-Mixed Dialysate x 4/session

#### **Storage Requirements**



- 80 5L Pre-mixed Dialysate Bags (40 Packs)
- 20 DIMI Cassette (Smaller and lighter)





### **DIMI** Usability Trial at a Glance

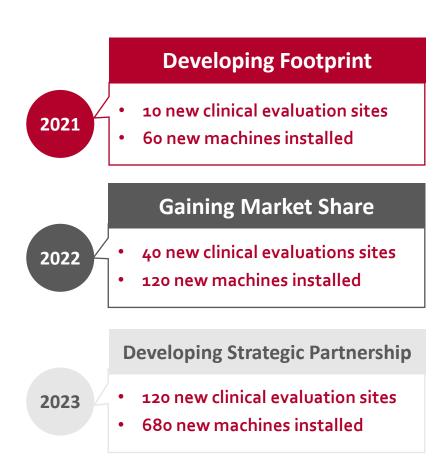
Phase	Phase 1: Run-in	Phase 2: In-Center Therapy Control Phase	Phase 3: In-Center to In-Home Transition Cross-over Phase	Phase 4: In-Home Therapy Test Phase
Duration	2 Weeks	6 Weeks	4 Weeks	6 Weeks
Description	Patient preliminary screening and base line exams	In-Center hemodialysis therapies per week using the DIMI	In-Center hemodialysis training of Care Partners with Subjects using the DIMI	Dialysis therapies performed by Care Partners with Subjects using the DIMI
Environment	In-Center	In-Center	In-Center	In-Home
Participants	Dialysis Nurses, Subjects	Dialysis Nurses, Subjects	Dialysis Nurses, Subjects, Care Partners	Subjects, Care Partners
<b>*****</b> 6-7 Clir	nical Sites			

- 12 Months Trial Duration6 Weeks In-Home Treatments
- **35** Evaluable Patients





### Dialco Strategic Priorities 2021 – 2023



#### **Dialco Commercialization Activities**



- Strengthen pipeline of tender and RFPs
- Partnership for VA
- Increase clinical evaluations
- Strategic partnership

# DIMI

- Execute IDE usability trial
- Achieve positive conversion from clinical trial to commercialization
- Expand intended use including PD
- Complete product portfolio
- Strategic partnership



### **Spectral Medical Inc.**

### Corporate Highlights



### **Upcoming Catalysts**

- Tigris New Sites
- DIMI Usability Trial CRO / IDE Sites Announced
- Dialco Private Funding
- SAMI Partnership
- Tigris Enrollment
- DIMI Usability Trial Enrollment
- Nasdaq listing
- DIMI PD FDA Clearance / HC Approval
- Tigris Interim Enrollment
- DIMI FDA Clearance for In-Home
- PMX FDA Approval

