

SIMERGENT

Affordable Home Dialysis

Contact: Steve J. Lindo
sjlindo@simergent.com
214-557-5868



Types of Dialysis-Hemodialysis



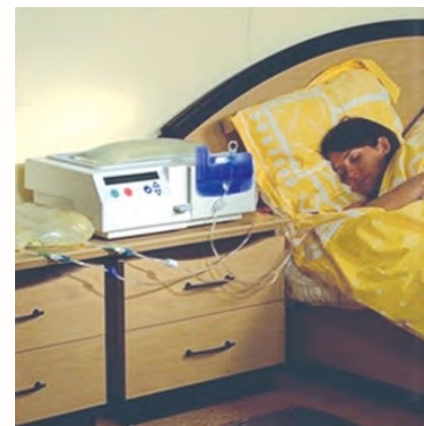
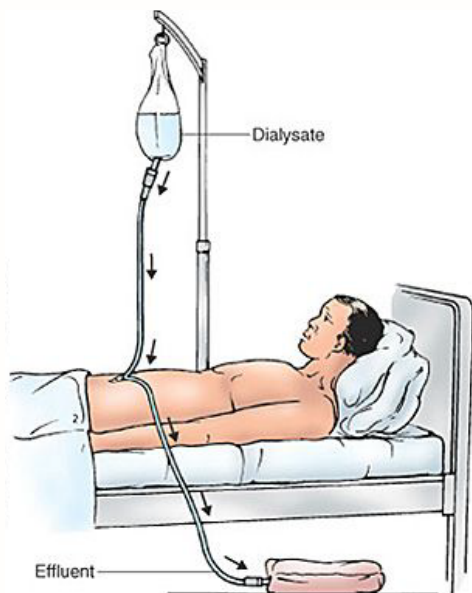
- Hemodialysis (HD)
 - Travel to clinic 3x / week
 - Device removes **blood** from patient, filters out toxins, & returns it



Simergent's Focus-Peritoneal Dialysis

- Peritoneal Dialysis (PD)

- Device delivers dextrose dialysate solution to patient, filters out toxins, & removes it (**no blood**)
- **Same outcomes as hemodialysis**
- \$3.9B Global Market
 - USA: 11% PD / 89% HD
 - Mexico: 56% PD / 44% HD



Patients are in desperate need of more accessible and affordable dialysis therapy

- Dialysis patients are 1% of Medicare patients, yet consume 7% of Medicare budget (\$34B)
- Globally, 2.3 million patients die each year
 - Can't afford or can't access dialysis
- Automated Peritoneal Dialysis is the answer

Baxter

Baxter HomeChoice System:

- 70% Global market share
- Up to \$20k selling price

TOO EXPENSIVE!!!



Simergent Team

Management Team

Steve J. Lindo

Co-Founder and CEO



Baxter

Rick Pendergraft, PhD

Co-Founder and CTO



Advisors / Partners

Several ex-Baxter and ex-startup executives (Sales, Marketing, International, CEO experience)

International nephrologists / nurses (US, Mexico, China, India, Brazil)

Regulatory:  EMERGO

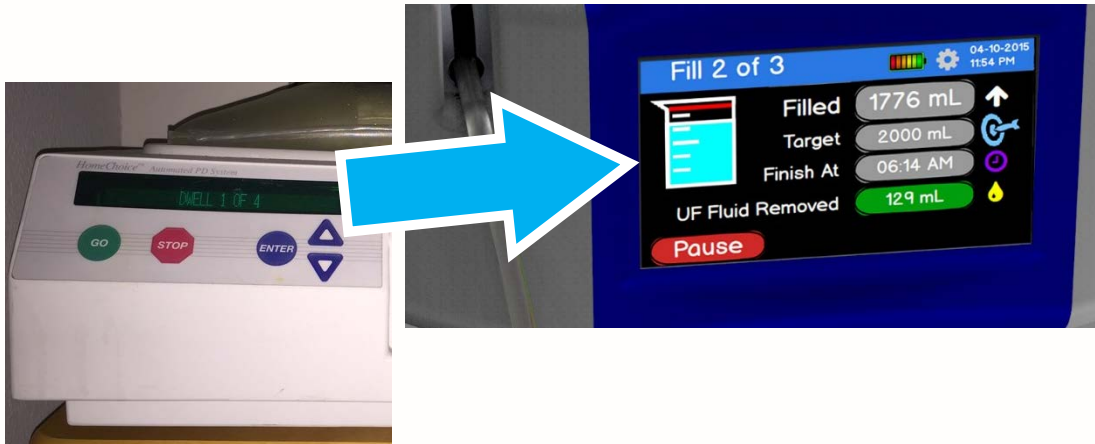


Disposables: **ThermoFisher**
SCIENTIFIC

SIMERGENT

Simergent's Archimedes System

- 85% less expensive (\$3k vs. \$5k-\$20k)
- Peritonitis-reduction technology
- Eliminates “drain pain”
- Quieter → better sleep
- Novel ultra-low power mode
- Easier to use



1st Formative Human Factors Study

6 Patients, 6 Nurses



Patient & Nurse Feedback on Archimedes

- Lower risk of peritonitis & associated hospitalizations

Patient: “It would help me with contamination. I wouldn't have to disconnect as much.”

- Provides patient mobility within the home

Patient: “That way I won't be in the bed all day. Just take it with me. Adds some of the normalcy to your life.”

Patient: “It'd be awesome to be able to move it around! Such an improvement over what I have!” (vs. Baxter HomeChoice)

- Faster training with fewer nursing staff
 - Currently takes ~1-5 weeks to train a new PD patient

Nurse: “This would cut training down in half!”

Barriers to Entry

- Provisional patent filed that allows us to achieve superior flow rates
- Trade secret APD therapy expertise
- Large med device OEMs acquire devices; they're not designed internally



Peritoneal Dialysis

IV Pumps

Home Hemodialysis

Incentives to Acquire Simergent

- US: Shift towards value-based care vs. fee for service; Medicare Advantage
- Ex-US:
 - Mexico
 - Highest incidence of kidney failure in the world
 - 56% use peritoneal dialysis vs. 11% in USA
 - India
 - 10k new patients in 5 years is worth **\$150M / yr**
 - China
 - 160k new patients in 5 years is worth **\$2.4B / yr, 20% CAGR**
 - “PD First” programs



Business Model

Simergent

- Licensing or acquisition deal at regulatory approval

Licensee or acquiring company

- Simergent device will enable sales of solutions and tubing sets

Baxter



**FRESENIUS
MEDICAL CARE**



2018 HealthTECH business plan competition



SIMERGENT

Regulatory Strategy

- Obtain US FDA 510(k) clearance
 - Seed Round:
 - Quality system (ISO 13485 & FDA)
 - Complete Beta prototype / safety software
 - Human factors study (in lieu of clinical trial)
 - Series A Round:
 - Verification & Validation testing
 - 510(k) clearance
- Leverage 510(k) to gain clearance in emerging markets

510(k) Predicate:
HomeChoice



Potential Partners

Baxter

- 70% Global APD market share



- 20% Global APD market share
- Home hemodialysis system



- 2016: Renal Care business formed



- Owns 1/3 of the dialysis clinics in the US



SIMERGENT Fundraising

2017:\$1.2M

Seed Round
(Closed)

- FDA and ISO 13485-compliant Quality System
- Beta prototype
- **Human Factors Study (completed Sep 2018)**

2018: \$2.5M

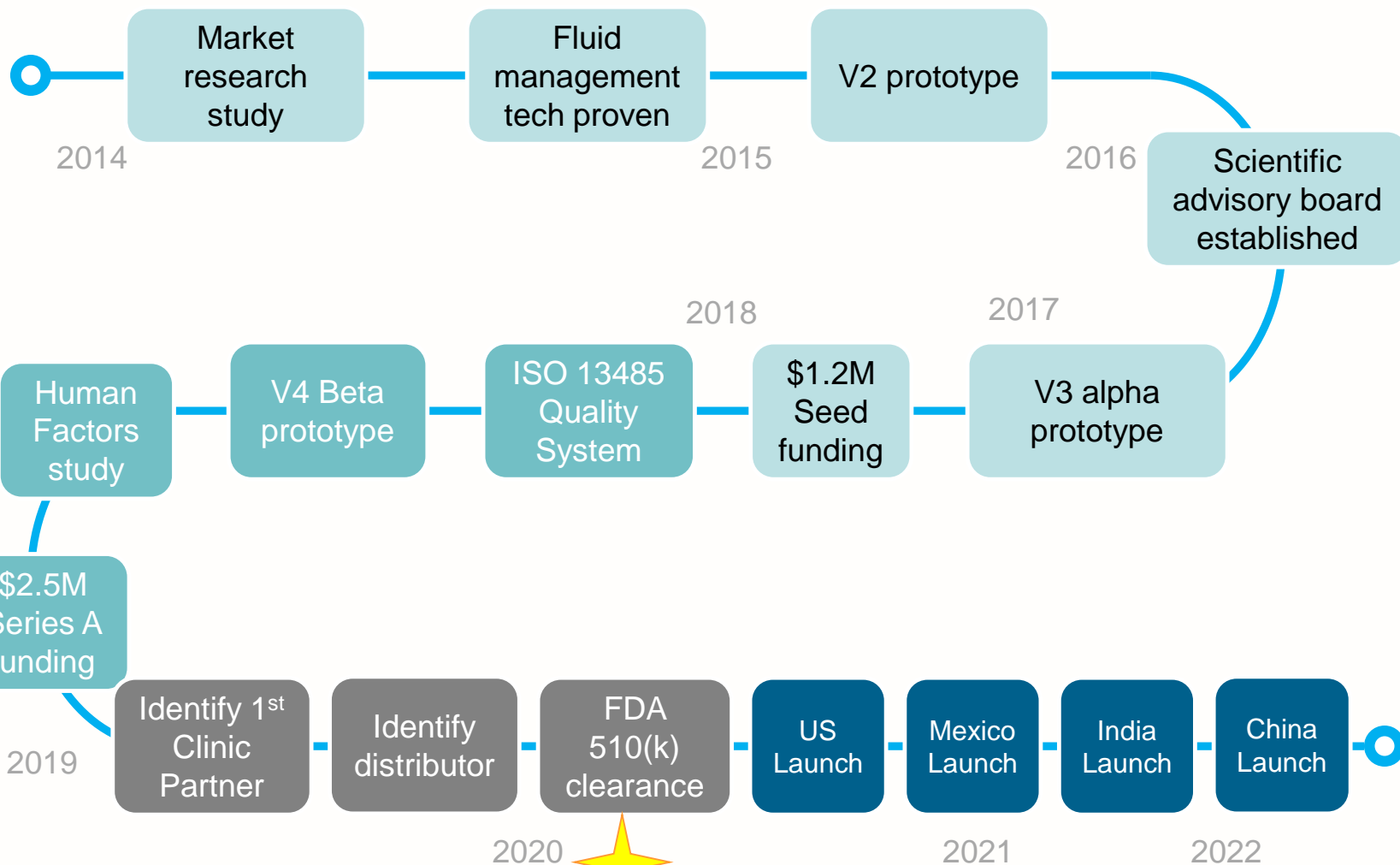
Series A Round
Currently Raising

- Operating & Business Staff
- Manufacturing Tooling
- Verification and Validation Testing
- **FDA 510(k) clearance**

Several nephrologist investors & significant founder investments

Program Schedule

Accomplishments



Design Freeze

Potential Acquisition

SIMERGENT

Comparable Exits – \$100M-\$300M, \$2B

Baxter

- **Peritoneal Dialysis:** HomeChoice – (DEKA 1994), ~\$200M, created \$1.5B/yr revenue
- **IV Pumps:** Spectrum – (Sigma 2012) \$190M, created \$1.7B/yr revenue
- **Home Hemodialysis:** Vivia – (DEKA 2016) ~\$300M

NxSTAGE

- **Hemodialysis Needles:** (Medisystems 2007) \$79M

FRESENIUS MEDICAL CARE

- **Home Hemodialysis:** (NxStage 2017) \$2B

Medtronic

- **Hemodialysis:** (Bellco 2016) \$119M

Financials (Device/Tubing)

	(In thousands)				
	<u>2020</u>	<u>2021</u>	<u>2022</u>	<u>2023</u>	<u>2024</u>
Sales Revenue	\$ 2,986	\$ 20,519	\$ 62,961	\$ 130,276	\$ 216,312
Cost of Sales	\$ 1,560	\$ 9,123	\$ 24,984	\$ 48,423	\$ 75,853
Gross Margin	\$ 1,425	\$ 11,396	\$ 37,978	\$ 81,853	\$ 140,459
<i>% of Sales</i>	47.7%	55.5%	60.3%	62.8%	64.9%
SG&A	\$1,693	\$8,453	\$18,332	\$29,964	\$49,752
R&D	\$1,480	\$2,680	\$4,407	\$9,119	\$15,142
Total Operating Expenses	\$3,173	\$11,133	\$22,739	\$39,083	\$64,894
EBITDA	(\$1,748)	\$263	\$15,238	\$42,770	\$75,566
<i>% of Sales</i>		1.3%	24.2%	32.8%	34.9%

Simergent Summary

- Raising \$2.5M Series A round
- Proven team of serial entrepreneurs
- Patient-centered, safer, easier to use product
- Large & growing market
- Addresses value-based care
- Solid industry relationships
- Tremendous healthcare impact!!!



Contact: Steve J. Lindo sjlindo@simergent.com

Phone: +01 214-557-5868