Smart Perfusion, LLC



VasoWave[™] Organ Transplantation System

Presenter: George Barr, President



A Medical Crisis





David Gerber, MD
Division Chief,
Organ Transplantation
UNC-Chapel Hill

Over 100,000 people in the U.S. are in end stage organ failure, and 400,000 are in organ failure that has not reached end stage.

"Fewer than 15% of patients actually listed for transplant end up receiving one -- this is because of a lack of innovation and progress."

Lack of Progress - Organ shortage

<u>attempt to slow deterioration</u>

Kidneys -12-24 hours; Livers 3-12 hours





Current Technology Attempts to Slow Deterioration



Ice coolers are used for transport, ~ 90% of current market

Kidney: Passive transporters (Waters, ORS)

Liver: No Technology Available Until Today!

Heart: Transmedics, not used clinically

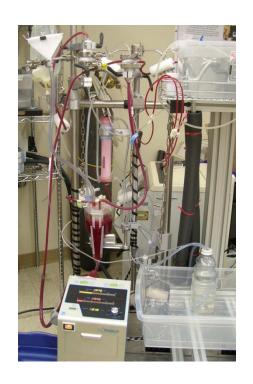
Various fluid based or cell based technologies are years from fruition, and they still won't be able to perfuse the entire organ without VasoWave





A Medical Solution





VasoWave at UNC Chapel Hill

VasoWave™ is Innovation.

It characterizes and conditions the organ to improve function:

kidneys – up to 72 hours livers – up to 24 hours

Histology shows that organs harvested after cardiac event and perfused on VasoWave are useable. These organs are now generally discarded.

This will create a new and significant potential source of organs.



Value Creation



Smart Perfusion creates *value*:

- For each patient in terms of health and productivity
- For a growing population of patients
- For transplant surgeons, who realize more income
- For transplant centers, with higher revenue and lower cost due to better outcomes
- For *insurance premium payers and taxpayers*, who currently pay for costs of end stage organ failure
- For Smart Perfusion owners





Business Model



- 90% of revenues are per use consumables and services
- Revenue sources are Medicare, Medicaid, Insurance
- Customers are
 - 58 Organ Procurement Organizations (OPOs)
 - 255 transplant centers
 - 35 transplant centers account for half of all transplants
 - Transplant surgeons are the decision makers
- Create a \$1.2 B market in the U.S.
- Create a \$5 B market globally





Milestones Met



- Three generations of VasoWave systems are fully bench tested for animal kidneys and livers. The systems are proven to be robust and easy to use.
- Scientific validation of increase in organ supply from Death by Cardiac Event over a two year period of animal testing has been completed.
- Human medical validation is in progress at UNC Chapel Hill, a regional transplant center.



Intellectual Property



Exclusive restricted license for transplant devices and processes:

- US patent 7,080,660B2, 7/25/06
- Pat. App 12/184701, 8/1/08
- Pat. App 12/942,497, 11/9/10
- Additional process with apparatus patent filing(s) in development
- PCT counterparts are awarded or pending



Conceptual drawing of the Characterization Module



FDA Approval Process



- Class I medical device
- 510K approval likely with a high degree of confidence
 - Predicate standard: Ice cooler with fluid flush capability (1976)
 - All 38 previous class entries (devices, solutions) received 510K approval
- Filing strategy
 - 513G filing and meeting
 - Presentation of test and manufacturing plan
 - Pre-IDE conference
 - GMP compliance
 - Approval



Investment Steps



- ► Founders: \$750k over six years
- ► First Round: currently raising \$1.5M at a \$5M valuation. Raised \$100k, in part from an MD
- ▶ Second Round: \$10.5M at a \$30M valuation
 (18 22 months from completion of First Round)
- ► Exit: \$150M- \$300M at 48 to 60 months



Milestones After \$1.5 million in Funding



6-12 months

- GMP prototype system built and tested
- Kidney, liver, heart (animal tests completed) (human organs tested)

13-22 months

- FDA Approval (510K)
- Professional management team hired
- Raise \$10.5M for sustaining progress

22-45 months

- Commercialize system and place with key transplant centers
- Cash break even endpoint



Financial Projections



(Dollars in 000's)	Year 1	Year 2	Year 3	Year 4	Year 5
Total Revenues	\$0	\$4576	\$25852	\$73868	\$142471
Cost of Goods Sold	\$0	\$1440	\$6433	\$17546	\$32877
Cross Profit	*	\$2426	¢40440	\$ 56222	\$40020 <i>4</i>
Gross Profit Gross Margin %	\$0 <i>nm</i>	\$3136 <i>68.5%</i>	\$19419 <i>75.1%</i>	\$56322 76.2 %	\$109394 <i>76.9%</i>
Gross Margin 70	11111	00.376	73.170	70.270	70.370
Operating Expense	\$4278	\$6551	\$10873	\$20482	\$35038
Margin	nm	nm	42.1%	27.7%	24.6%
Pro tax Operating Income	(\$4278)	(\$2.44E)	\$8546	\$35840	\$74356
Pre-tax Operating Income		(\$3,415)	33.1%	48.5%	52.3%
Pre-tax Op Inc Margin	nm	nm	33. I /0	40.5 /0	<i>32.3 /</i> 0

Exit Strategies



Sell, License, Joint Venture, M&A, Build to Positive Cash Flow

Potential targets include
Organ Recovery Systems, Waters, Transmedics,
Johnson and Johnson
European and Asian Partners

IPO

Potential liquidity at milestones between 18 and 48 months



The Smart Perfusion Team





George Barr, MBA, Founder, CEO, 29 years commercializing technology in medical and industrial markets



Don Faulkner, Engineer, Founder, CTO, a creator of IP, expert on fluids, pumping systems and materials science



David Gerber, MD
Chief Medical Officer
Division Chief, Organ
Transplantation at
UNC-Chapel Hill



John Robertson, VMD, PhD, CSO, a creator of IP, conducting translational animal research and testing, FDA expert



George Blanar, Ph.D. Former VP, Carilion Biomedical Institute, Carilion Health System, over 20 years of entrepreneurial and business consulting experience to engineering and biomedical companies



Summary



Smart Perfusion LLC Increase organ supply for transplant

Team Medical, scientific, engineering, business

professionals

Opportunity Federally funded market (Medicare line item)

Product Patented/pending technology and procedures

in a transplant organ support system

Business Model 90% of Revenues are Per Use Consumable and

Service Fees

Competition VasoWave surpasses all current technologies

Financials Long-term growth, mid-term liquidity

Seed Funding Clearly identified milestones and exit at Year 4

or 5 with a 10X return for \$1.5 M investment







VasoWave[™]
Organ Transplantation System
Contact: George Barr
704 241 5029

gbarr@smartperfusion.com www.smartperfusion.com

