Affinity Therapeutics

Drug delivery grafts for immediate vascular access and reduced failure rates in hemodialysis patients.

Total Interviews: 128

Weekly Average: 13

Sean T. Zuckerman, Horst von Recum, Paul Olson

PI C Level Industry Expert
What we thought initially

- ~400,000 Hemodialysis pts in US
- ~80,000 pts with AV Graft
- Target is ~50% of market

Source: US Renal Data Service, 2013 Annual Report
What we thought initially

- Affinity’s graft would be so good we could increase market share of grafts

TAM = 400,000 pts
SAM = >>> 80,000 pts
Target = >>> 40,000 pts

Source: US Renal Data Service, 2013 Annual Report
Vascular Access

- Long term vascular access critical for hemodialysis
- Arteriovenous (AV) grafts common but suboptimal option
Coated AV Graft for Long Term Vascular Access

Normal AV Graft lifespan

Affinity’s coating

Affinity’s Graft lifespan

Smooth muscle cells
Steve said...

Get OUT!!!
So we did...

- Interviewed 128 customers starting with
  - Nephrologists
  - Vascular Surgeons
  - National Kidney Foundation & Kidney Disease Increasing Global Outcomes (KDIGO)
So we did...

- Interviewed 128 potential customers
  - Nephrologists
  - Vascular Surgeons
  - National Kidney Foundation & Kidney Disease Increasing Global Outcomes (KDIGO)
  - Dialysis Clinics
  - More nephrologists
  - Patients
Initial Canvas

Key Partners
- CROs
- Value Analysis Committee
- Medical Device Co’s

Key Activities
- Preclinical studies
- Large animal Proof of Concept studies
- Key Resources
- IP

Value Propositions
- Decrease stenosis rates
- Increase sales
- Ease pain & hassle

Customer Relationships
- Publish
- Channels
- Licensing
- Acquisition

Customer Segments
- Vascular Surgeons & Nephrologists
- Medical Device Co’s
- Dialysis Pts

Cost Structure
- CROs

Revenue Streams
- SBIR grants
# Initial Canvas

<table>
<thead>
<tr>
<th>Value Propositions</th>
<th>Customer Relationships</th>
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<tr>
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Week 2 Canvas

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Customer Interviews → Patient Workflow

- Nephrologist (loosely) owns the patient
- Vascular surgeons typically choose access type
  - Sometimes interventionalist implants

1. Patient (Pt) visits Nephrologist
2. Nephrologist refers Pt to Vascular Surgeon
3. Vascular Surgeon implants Vascular Access
4. Pt proceeds to DIALYSIS!
5. Pt returns to Vascular Surgeon
6. Pt returns to Nephrologist
7. Pt proceeds to DIALYSIS!
Piggy-Back our MVP on Marketed Gore Triple-Layered AcuSeal™

- “Sandwich” coating between layers
- Newer product = smaller market share
# Week 6 Canvas

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## Key Resources
- IP

## Customer Relationships
- Publish: JAMA, Circulation, J Vasc Surgery,
- Conference: Kidney Week
- Licensing
- Acquisition

## Customer Segments
- Vascular Surgeons, Nephrologists, Interventionalists
- Decision Maker @ Medical Device Co’s
- Dialysis Pts

## Cost Structure
- CROs

## Revenue Streams
- SBIR grants

## Additional Notes
- Increase graft life 25%
- Increase sales
- Ease pain & hassle
- Decrease stenosis rates 50%
- Center for Devices & Radiological Health
- Admin Contractor @ CMS
- KOL

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**Week 6/26-30**
- **Monday: Preclinical Studies**
- **Tuesday: Large Animal Proof of Concept Studies**
- **Wednesday: Increase Sales**
- **Thursday: Ease Pain & Hassle**
- **Friday: Administrative Management**
# Week 6 Canvas

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### Cost Structure
- CROs

### Revenue Streams
- SBIR grants
Revisited the Graft Market

- CPT Code: ~$1000 reimbursement
- $40 million Target Market
- PMA likely costs $10s of millions...

Source: US Renal Data Service, 2013 Annual Report
Revisited the Graft Market

- CPT Code: ~$1000 reimbursement
- $40 million Target Market
- PMA likely costs $10s of millions...
- Rethink MVP

TAM = 400,000 pts
SAM = $80 Million
Target = $40 Million

Source: US Renal Data Service, 2013 Annual Report
2 Possible MVPs

Coated Graft → FDA: Likely PMA (Predicate → CDRH alone)

Stand alone "wrap" → FDA: Likely PMA (CDRH + CDER)
2 Possible MVPs

Coated Graft → FDA: Likely PMA
(Predicate → CDRH alone)
Existing CPT code coverage

Stand alone "wrap" → FDA: Likely PMA
(CDRH + CDER)
New HCPC code (~3 yr)
2 Possible MVPs

Coated Graft

FDA: Likely PMA
(Predicate $\rightarrow$ CDRH alone)
Existing CPT code coverage

FDA: Likely PMA
(CDRH + CDER)
New HCPC code ($\sim$3 yr)

Stand alone “wrap”
Drug-eluting Wrap: Works with Fistulas or AV Grafts

Potential wrap market is $\geq 3X$ AV Graft market size!
Design Flaw Nearly Derailed Concept

Interview 82 = potential, “Uh Oh” moment...

Adapted from Paulson WD et al. Nephrol Dial Transplant (2012);27: 1219-1224
Interview 116 (KOL)
Allowed us to Detect and Correct: Wrap Venous Tissue Only
## Final Canvas

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### Key Resources
- Licensed IP
- Affinity’s IP
- Advisory Board

### Key Activities
- Freedom to Operate
- License IP
- Preclinical studies
- Large animal studies

### Value Propositions
- Decrease stenosis rates 50%
- Increase graft life 25%
- Increase time to 1st intervention 25%
- Increase sales
- Ease pain & hassle

### Customer Relationships
- Publish: JAMA, Circulation, J Vasc Surgery,
- Conference: Kidney Week
- Licensing
- Direct Sales

### Customer Segments
- Vascular Surgeons, Nephrologists, Interventionalists
- Decision Maker @ Medical Device Co’s
- Dialysis Pts

### Cost Structure
- CROs
- IP costs

### Revenue Streams
- SBIR grants
- Licensing
- Milestone Payments
Final Canvas CS-VP

Value Propositions
- Decrease stenosis rates 50%
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- Increase sales
- Ease pain & hassle

Customer Relationships
- Publish: JAMA, Circulation, J Vasc Surgery,
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- Licensing
- Direct Sales

Customer Segments
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Increase sales
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Direct Sales
Vascular Surgeons, Nephrologists, Interventionalists
Decision Maker @ Medical Device Co’s
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Final Canvas KA-KR-KP

**Key Partners**
- CROs
- Value Analysis Committee
- Medical Device Co’s
- Nat’l Kidney Foundation
- Center for Devices & Radiological Health
- Admin Contractor @ CMS
- KOL

**Key Activities**
- Freedom to Operate
- License IP
- Preclinical studies
- Large animal studies

**Key Resources**
- Licensed IP
- Affinity’s IP
- Advisory Board
What’s next?

• Freedom to Operate

• Continue vetting drug-eluting AV graft and wrap MVPs
  • Talk with Gore re: interest (possibly Bard)

• Cultivate relationship with KOL Dr. Timmy Lee at UAB (Interview 116)
  • Potential clinical and commercial relationship.

• Use Sales and Medical Science relations to build out KOL and Institutional relationships
  • Harvard-associated hospitals
  • Washington University/Barnes-Jewish
  • University Hospital at Case Medical Center
Phase II SBIR Grant

• Affinity plans to submit a Phase II SBIR proposal after a minor pivot.

• This proposal will be submitted in 2016 because Affinity has a two year SHIFT award.

Investment Readiness Level

4. Complete First-Pass Canvas
3. Problem/Solution Validation
2. Mkt Size/Competitive Analysis
1. Validate Metrics That Matter
9. Validate Left Side of Canvas
8. Validate Right Side of Canvas
7. Prototype High Fidelity MVP
6. Prototype Low Fidelity MVP
5. Validate Product/Market Fit
4. Validate Product/Market Fit
3. Problem/Solution Validation
2. Mkt Size/Competitive Analysis
1. Complete First-Pass Canvas
Final Slide – whew!

• Final Video on Youtube: http://youtu.be/SYWmiJgDnAs

Sean Zuckerman  
PI

Horst von Recum  
C Level

Paul Olson  
Industry Expert