3rd Annual Academic & Industry Intersection Conference: Commercialization of Discoveries
February 9, 2012 | Emory Conference Center
Georgia Success Stories

- **Moderator:** Todd Sherer, PhD, Director Technology Transfer, Emory University
- Christian Larsen, MD, DPhil, Joseph Brown Whitehead Professor and Chairman, Department of Surgery, Emory University School of Medicine
- Mary Beth Harler, Executive Director, Global Development, Bristol-Myers Squibb
- Joseph M. Patti, M.S.P.H., Ph.D., Co-Founder, Chief Scientific Officer & Senior Vice President of Research and Development, Inhibitex, Inc.
- Daniel White, MBA, President and Chief Executive Officer, Clearside Biomedical, Inc.
- Mark R. Prausnitz, PhD, Regents’ Professor and Love Family Professor in Chemical & Biomolecular Engineering, School of Chemical Engineering, Georgia Institute of Technology
Costimulation Blockade: A new treatment paradigm for Renal Transplantation

An Industry Academic Partnership from Discovery to Delivery

Christian P. Larsen
Emory Transplant Center
Emory University

Mary Beth Harler
Bristol-Myers Squibb
Immunosuppression Regimens for Renal Transplant

- **Calcineurin Inhibitor (CNI)** (cyclosporine or tacrolimus)
- **Mycophenolate**
- **Steroids**
- **Basiliximab or Thymoglobulin Induction**

*Time post transplant*
Reduction in rejection fails to improve long-term Renal allograft survival

Acute Rejection, Months 0–6

Chronic Allograft Nephropathy
Death with functioning graft


Costimulation Blockade - Selective immunosuppression

Calcineurin-inhibitors near ubiquitous target distribution

Costimulation molecule expression restricted to immune system

Immunosuppression

Hypertension, Hyperlipidemia, Diabetes, Nephrotoxicity
Emory Transplant Center – Not for the Profession, for the people
Bristol-Myers & Emory Transplant Center
Costimulation Blockade a new immunosuppressive paradigm
1987-2012

Belatacept
Phase II
Phase III
Investigator-initiated

Clinical Application

Discovery
1987-2011
Costimulatory Molecules on DC
CTLA4-Ig inhibits rejection
CD28 blockade and tolerance

Translation

Translational Studies-
Yerkes Primate Center
CD28 a Critical Costimulatory Pathway

B7-1 (CD80) - B7-2 (CD86)

MHC - TCR

Enhanced T cell survival
Enhanced bioenergetics
Cytokine synthesis
Abatacept (CTLA4-Ig): the prototypic CD28 costimulation pathway blocker

- Ig Fusion protein
- Soluble receptor
- Competitive inhibitor of B7/CD28
- Immunologic Tool
- Candidate Therapeutic
Transplantation®
RAPID COMMUNICATION

TRANSPLANTATION TOLERANCE INDUCED BY CTLA4-Ig

THOMAS C. PEARSON, DIANE Z. ALEXANDER, KEVIN J. WINN, PETER S. LINSLEY, ROBIN P. LOWRY, and CHRISTIAN P. LARSEN

Departments of Surgery, Pathology, and Medicine, Emory University School of Medicine, Atlanta, Georgia 30322; and Bristol-Myers Squibb Pharmaceutical Research Institute, Seattle, Washington 98121

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Graph showing percent survival over time with different treatment groups.
Long-term acceptance of skin and cardiac allografts after blocking CD40 and CD28 pathways

Christian P. Larsen*, Eric T. Elwood*, Diane Z. Alexander*, Shannon C. Ritchie*, Rose Hendrix*, Carol Tucker-Burden*, Hong Rae Cho*, Alejandro Aruffo†, Diane Hollenbaugh†, Peter S. Linsley†, Kevin J. Winn‡ & Thomas C. Pearson*
Effect of CTLA4-Ig on renal allograft survival in Rhesus macaques

CTLA4-Ig (16 mg/kg)
Rational Development of LEA29Y (belatacept), a High-Affinity Variant of CTLA4-Ig with Potent Immunosuppressive Properties

Extracellular portion of CTLA4 (CD152)

Serum Cr

Larsen, Pearson et al AJT 2005
Belatacept maintains excellent Patient and Graft Survival
Patients Surviving with Functioning Graft at Year 3 - BENEFIT

Belatacept MI (n = 219) 92
Belatacept LI (n = 226) 92
CsA (n = 221) 89

3.5 (97.3% CI = -2.8, 10.0)
3.3 (97.3% CI = -2.9, 9.8)
Calculated GFR Over Time – 24 months
Study -008

Slope (95%CI), mL/min/1.73 m²/year
- Belatacept MI: 1.32 (0.07, 2.58)
- Belatacept LI: 1.22 (-0.01, 2.44)
- Cyclosporine: -1.96 (-3.22, -0.70)

$\Delta$ from CsA
- 12.2 – 12.7
- 15.1 – 15.3
- 17.5 – 17.6
• **People- BMS Scientists, Emory Clinical Scientists**

• **Emory Focus**
  - Dendritic Cell Biology, Mechanisms of Rejection, develop a pathway blocker
  - Get a grant, get a publication

• **BMS Focus**
  - Dissect a pathway, secure intellectual property, develop therapeutics

• **Results MTA, JEM publications, NIH R29, R01**

• **Common Interests: develop tools, explore biology**

• **Challenges- MTA, Exclusivity, Freedom to present, publish, speed**
Definition of Therapeutic Area and Niche

1994-2000

- **Emory Focus**
  - Mechanisms of Rejection, Immune Tolerance, Knowledge
  - Grants, Publications, develop a translational program
  - Lead the field, be first

- **BMS Focus**
  - Focus work where the ip is held, don’t wander
  - Learn about transplantation, make go no go decisions

- **Results:** Therapeutic Potential Defined, *Nature*, R01s renewed, Program Project Grant, Philanthropy, Joint Patents

- **Common Interests:** Trust, Common Goals

- **Challenges- Failed Strategic Agreement, Timing of presentation, publish, delayed access to compounds loss of academic leadership**
Preclinical Evaluation

1997-2003

- **Emory Focus**
  - Develop immune Tolerance,
  - Grants, Publication, translational program, lead new trial
- **BMS Focus**
  - Deep understanding transplantation
  - Serious- go no go decisions
  - Define regulatory path to approval
- **Results:** Publications *Nature Medicine, JCI, Preclinical Contracts, Program Project Grant for Non-human primate studies, Recognition within Emory*
- **Common Interests:** Therapeutic Development, exploration of related indications, Trust, Candor, mutual understanding
- **Challenges:** Freedom to present, publish, loss of exclusivity
Clinical Development

- Emory Focus
  - Leadership of Clinical Trials, Continued access for next generation preclinical studies

- BMS Focus
  - Trial and Development Program Design
  - Entre to best of Transplant Community
  - Rigorous and Rapid Trial conduct
  - Respected Academic Partners for FDA and community interaction

- Results: Successful Phase II, Phase III, NEJM

- Challenges- Role of new clinical academic partners, petty politics of clinical investigations
Emory Focus
- Commitment to safe and effective real world implementation
- Leadership of Next-generation, NIH sponsored Investigator initiated Clinical Trials

BMS Focus
- Safety
- FDA compliance
- Careful Communication
- Market share

Results: Belatacept as Standard of Care at Emory, NIH sponsored trial enrolling, Impact of Belatacept in transplantation TBD

Challenges:
Emory & Bristol-Myers Squibb: Successes and Challenges

Mary Beth Harler, MD
Bristol-Myers Squibb
Two entities with complementary areas of interest / expertise

**Emory**
- Wealth of experience in transplantation and immunology
- Capability and expertise in a wide range of pre-clinical transplant models and technology platforms for exploring biological mechanisms
- Long-standing research interest in costimulatory blockade
- Generated proof of concept for belatacept as a potential therapy for transplant patients

**BMS**
- Deep understanding of costimulatory pathway re: potential for therapeutic targets
- Capacity to conduct large scale clinical trials and gain registration
Positives

• Partnership
  • Emory has demonstrated the ability to pursue academic questions AND make sure the business needs of BMS are met

• Complementary skills/capabilities
  • Emory has the technical experience and resources required to address questions BMS could not easily address
    • Clinical insights had significant impact on clinical development plan and data interpretation

• “Deep bench”
  • Emory has numerous experts in the field with diverse backgrounds and areas of interest – enables ability to address many transplant-related questions
Challenges

• Time required to execute contracts
• Reports on studies sometimes slow to be completed
• Potential for experiments or publications not previously discussed
• BMS and Emory collaborations could have been more scientifically rigorous in early studies
  • More dose ranging studies
  • Deeper analysis of issues of known interest in transplantation
Key Learnings

• Both academic and business needs can be met, but requires awareness and “tending to”
  • Mutual respect
  • Appreciation of one another’s needs
  • Communication

• Be proactive about the pragmatic aspects of a partnership
  • Master agreements to facilitate faster contracting
  • Clarity on expectations for both parties (what, when, how)

• The Emory / BMS collaboration provides proof that academia and industry can build a sustainable partnership to develop new therapies
Treating and Preventing Infectious Disease
Inhibitex was Created from IP from Multiple Academic Institutions

- Trinity College, Ireland
- University of Pavia, Italy
- Washington University
- University of Alabama at Birmingham

1994 – 1997
$640,000
Abs inhibits attachment to extracellular matrix components thereby preventing microbial colonization

Antibodies bind MSCRAMM with high affinity and specificity and enhance microbial clearance via opsonophagocytosis

Anti-MSCRAMM Ab
MSCRAMM
S. aureus

Binding site for MSCRAMM
Three IND’s Resulting from Collaboration with Academic Institutions

- SA-IVIG (human immune globulin enriched for *S. aureus* anti-ClfA Abs)
  - Phase 1/2

- Veronate (INH-A21; human immune globulin enriched for *S. aureus* anti-ClfA Abs and *S. epidermidis* anti-SdrG Abs)
  - Phase 1, Phase 2, Phase 3

- Aurexis (SA-mAb; humanized monoclonal anti-ClfA Ab)
  - Phase 1, Phase 2
Bolt on Additional IP from Additional Academic Institutions

Yale University

University of Minnesota

Fungal MSCRAMMs
### Inhibitex Product Pipeline - 2005

<table>
<thead>
<tr>
<th>Product Candidates</th>
<th>Research</th>
<th>Pre-Clinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
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<tr>
<td>Diagnostics (3M)</td>
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<td>Aurexis - Bacteremia</td>
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<td>Staph Vaccine (Wyeth)</td>
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<td>Enterococcal mAb (Dyax)</td>
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<td>S. epidermidis mAb</td>
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<td>Candida mAb</td>
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**First product launch expected in late 2007**

- **Treatment and prevention of S. aureus infections**
- **Active vaccine against staph**
- **Monoclonal antibodies for the prevention or treatment of serious infections**
Life Cycle Management = “Survival”

- IPO
- Veronate Phase 3
- Disappointment
- Inhibitex 2 Begins
Inhibitex Version 2

Katholieke University, Belgium

Cardiff University, UK

Cardiff University, UK

University of Georgia

Acquired Fermavir for ≈$18M of INHX stock 2007

In-licensed HCV and HIV IP 2007
### Pipeline of Differentiated Anti-infective Products - 2008

<table>
<thead>
<tr>
<th>Category</th>
<th>Discovery</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III/Marketed</th>
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<tr>
<td><strong>Antiviral</strong></td>
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<td>FV-100 (shingles)</td>
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<td>HIV integrase</td>
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<td>CMV nucleoside</td>
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<td>HCV polymerase</td>
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<td>inhibitors</td>
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<td><strong>Antibacterial</strong></td>
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<td>Aurexis (SAB)</td>
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<td>Staph vaccine</td>
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<td>Wyeth</td>
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<td>Bacterial &amp; fungal</td>
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<td>diagnostics</td>
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### Pipeline of Differentiated Anti-Infective Products - 2009

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<th>INDICATION</th>
<th>PRECLINICAL</th>
<th>PHASE I</th>
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<td>Shingles (FV-100)</td>
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<td>Hepatitis C (INX-189; Nucleotide NS5b Inhibitor)</td>
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<tr>
<td>Prevention of S. aureus Infections (Vaccine)</td>
<td>Wyeth</td>
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*Aurexis®, a humanized mAb for the prevention/treatment of S. aureus infections has successfully completed Phase IIa trial; seeking to out-license*
Life Cycle Management = “Maybe We Have a Chance”
# Pipeline of Differentiated Anti-Infective Products - 2012

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<thead>
<tr>
<th></th>
<th>Preclinical</th>
<th>Phase 1a</th>
<th>Phase 1b</th>
<th>Phase 2</th>
<th>Phase 3</th>
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<td><strong>INX-189</strong></td>
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<td><strong>HCV Back-Up/Follow-On</strong></td>
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<td><strong>Staph Infections SAg4</strong></td>
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- INX-189: P1b ext. data Q1 2012, P2 GT 2/3 RVR data Q1 2012
- FV-100: Submit P2b protocol to FDA Q4 2011
- HCV Back-Up/Follow-On: IND targeted for 2H 2012
- Staph Infections SAg4: Phase 1/2 trial initiated Q3 2011
Life Cycle Management = “We Did It”

- IPO
- Veronate Phase 3
- Disappointment
- Inhibitex 2 Begins
- Phase 1 HCV Data
- More Phase 1 HCV Data
- Announce BMS $2.5 B Acquisition
“Everybody Wins”

- Academic institutions have greater confidence in achieving milestone payouts (look smart for working with INHX)
- Academic scientists have increased their odds of receiving royalties on their inventions (kudo’s for inventing a valuable asset)
- Employees finally realize the benefits of option grants (now worth more than the paper)
- Shareholders get a significant return on investment
- Most importantly, patients will benefit from novel, life-saving therapies
What’s Next?
Founded 2011
Georgia Tech Institute for Bioengineering and Bioscience
Emory University School of Medicine
An ophthalmic therapeutics company improving drug performance using a proprietary tissue targeted microinjection platform

- Successful management track record developing / commercializing drugs and devices in ophthalmology
- Simple, safe and effective microinjection platform
- Developing tissue targeted products containing known drug actives
- Patented protected

...the only non-surgical application for dosing drugs to distinct eye tissues, such as retina, trabecular meshwork and corneal stroma
A collaborative effort between Emory and Georgia Tech

- **Mark Prausnitz, PhD**—Founder (Prof. GA Tech)
  - Professor of Chemical Engineering, PhD with Langer at MIT
  - Pioneer of microneedle technology
- **Henry Edelhauser, PhD**—Founder (Prof. Emory)
  - Professor of Ophthalmology and ocular drug delivery innovator
  - Developer of BSS Plus (Alcon)
- **Samirkumar Patel, PhD**—Founder (Post doc GA Tech)
  - Ocular microneedle research doctoral thesis
- **Vladimir Zarnitsyn, PhD**—Founder (Research scientist GA Tech)
  - Microneedle fabrication (10 years in drug delivery, microneedles)
- **Harold Shlevin, PhD**—External Advisor
  - 25-year bioscience executive, Biosciences Manager of GA Tech Advanced Technology Development Center
  - Former President & CEO Solvay Pharmaceuticals; Executive roles at CIBA Vision, Bausch & Lomb
TISSUE TARGETING WITHIN THE EYE

500 nm particles in SCS of pig eye
History of the research

• 1993-1994: worked for ORBIS International
• 1995: started microneedle research at Georgia Tech
• 1998: published first paper and filed first patent application on microneedles
• 1999: started Redeon to commercialize microneedles for drug delivery to skin (Redon sold to BioValve in 2001)
• 2001: initiated ophthalmic microneedle collaboration with Henry Edelhauser
• 2007: published first paper and filed first patent application on ophthalmic microneedles
• 2008: “mistakenly” injected into suprachoroidal space
• 2010-2011: decided to form a company to commercialize ophthalmic microneedles (technology, champion, CEO)
Companies have generated high value by providing improved dosing into the eye

The market has primarily been focused on drug delivery via penetration into the globe, which is complicated and cumbersome

... but, there is a significant need for targeting distinct tissues with a simple procedure that improves safety and duration
Intravitreal injections (3 MM worldwide) are the standard of care for many retinal diseases, yet poorly target the site of action...

IVT steroids, about 10% of the total, lead to elevated intraocular pressure, cataracts, and leave the eye susceptible to infection.
The suprachoroidal space (SCS) is a better location for targeting the retina and choroid...

- Anatomical space between the choroid and sclera
- Holds up to 200 µL
- Dose spreads around the choroid and retina
- Drugs in the SCS can provide sustained release
- Isolates drug away from anterior segment

... because distribution of drug is isolated to the site of disease
The Clearside Biomedical microinjection system delivering to the SCS demonstrates a marked increase in sustained release duration of TA in in-vivo studies.

- Injection of 2% Triesence ® (Alcon) into rabbit eyes in vivo
- SCS microinjection vs IVT injections
- 2 mg dose
- 100 µL volume

SCS TA has a half-life 3x greater than that of IVT TA enabling a reduction in the typical number of injections of 4-5 per year to 1-2 per year for effective treatment.
The Clearside Biomedical microinjection system targeting the SCS leads to improved chorioretinal selectivity...

- Isolate drug in the choroid and retina at therapeutic levels
- Higher drug exposure to the choroid and retina: 8 x greater AUC
- Lower drug exposure to lens and anterior: 15x lens and 10x anterior lower AUC
- Formal GLP safety needs to be completed however, no evidence of toxicity has been observed

The potential for improvement in chorioretinal selectivity can be realized in a limitless range of compounds
Clearside Biomedical’s SCS TA minimizes exposure to the lens and anterior segment by an order of magnitude versus IVT TA

<table>
<thead>
<tr>
<th></th>
<th>SCS Microinjection</th>
<th>Intravitreal Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle size</td>
<td>33-34 gauge</td>
<td>27-30 gauge</td>
</tr>
<tr>
<td>Full thickness</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>penetration</td>
<td></td>
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<tr>
<td>Needle track</td>
<td>&lt; 1 mm</td>
<td>&gt; 5 mm</td>
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</table>

**Triamcinolone (2mg dose)**

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<tr>
<th></th>
<th>SCS Microinjection</th>
<th>Intravitreal Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of TA in lens +</td>
<td>&lt; 0.5 %</td>
<td>9-10 %</td>
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<tr>
<td>anterior segment</td>
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<tr>
<td>7 days</td>
<td>6.5 ± 1 µg</td>
<td>171 ± 7 µg</td>
</tr>
<tr>
<td>30 days</td>
<td>3.6 ± 1 µg</td>
<td>44 ± 3 µg</td>
</tr>
<tr>
<td>60 days</td>
<td>3 ± 1 µg</td>
<td>12 ± 1 µg</td>
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</table>

Clinical experience reports a 50% decrease in incidence of IOP increase when steroid is placed in the back half of the vitreous
Founded 2011
The creation of a start-up
With the results in hand
Interest level from external sources
Team interested in a start up,

The team sought advice from Harold Shlevin of Georgia Tech Venture Lab for advice.

“...may the force be with you”
The Advice: Company formation requires three pillars

- **Talent** – “leadership team that is fool-hardy enough to try it”
- **Technology** – “a crazy idea that just may work”
- **Money** – “Investment partners that believe it”
Clearside management team has extensive industry experience and technical expertise in ophthalmology and drug delivery

- Daniel White, MBA—President & CEO
  - Alimera, Stiefel, GSK, Ciba Vision
  - Experienced entrepreneur in ophthalmology, dermatology and drug formulation

- Ben Yerxa, PhD—VP R&D
  - Inspire, Parion, Burroughs Wellcome
  - R&D innovator in ophthalmology and pulmonary medicine
Brief Incorporation History

- May – approached Daniel White to discuss a leadership role
- May – Daniel White returns for a second look
- June – team agreed on
  - The Founder Equity
  - The Financing Plan pro forma
- August – Daniel White completes diligence and begins negotiations for the technology
- August – Daniel White hires Ben Yerxa as VP, R&D
- October – Agreements negotiated and signed
- October – Development Plans complete
- October – Initiate parallel path fund raising process
  - Drafted PPM and planned for angel round
  - Approached 52 VCs in a 6 week period – seeking operational experience in ophthalmology
- December – Term sheet received with Hatteras for $4 MM
- January – Closed initial investment
- February – Closed remaining investments
Seed Funding

• $25,000 loan to company for set up
• $100,000 loan to company for assembling management and fund raising
• $28,000 GRA grant for Phase 1a for prototype development
• $22,000 GRA grant for Phase 1b for pharmacodynamic experiments

WHAT TO DO NEXT IN THIS CRAZY ECONOMY?

Angels or Venture Capital
For Immediate Release

CLEARSIDE BIOMEDICAL LAUNCHED WITH PIPELINE AND TECHNOLOGY FOCUSED ON DRUGS DELIVERED TO THE BACK OF THE EYE

- Hatteras Venture Partners Leads $4 million Series A Financing

ATLANTA and DURHAM, January 5, 2012—Ophthalmic startup Clearside Biomedical and Hatteras Venture Partners announce today that they have launched the company with a $4,000,000 Series A venture financing

Key Investor – Christy Shaffer, Hatteras Discovery:

A belief that entrepreneurial innovation will create valuable new products that will transform the practice of medicine and create value for our investors.
Recipe for a happy ending ...

• World class inventors
• Market transforming technology validated by the outside world
• Management recognized for success in the target market
• Experience as an entrepreneur
• Investor connection –
  – Experience in the target market
  – Relationship with management
An ophthalmic therapeutics company improving drug performance using a proprietary tissue targeted microinjection platform

- Successful management track record developing/commercializing drugs and devices in ophthalmology
- Simple, safe and effective microinjection platform
- Developing tissue targeted therapeutics
- Patented protected

A capital efficient investment in an ophthalmic company developing therapeutics through a proprietary, tissue targeted microinjection platform