Exclusive Opportunity

Encapsulation for Islet Cell Transplantation
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Problem: Type 1 Diabetes

- 1.8M people affected in U.S., 37M WW by 2030

- Complications:
  - heart disease, blindness, kidney damage, nerve damage

- Treatments:
  - insulin injections/pump
  - monitor blood sugar levels
  - healthy diet and regular exercise
Solution: Islet Cell Transplantation

Benefits:
- patients become insulin independent

Limitations:
- limited donor population
- potent immunosuppression drugs required

Improved Methodologies Needed To Realize the Potential of Islet Transplantation
Novel Cell Encapsulation Formulation

Significantly Enhances Survival of Porcine Islets in Immunosuppressed Diabetic Mice

Ave days function ± SE = 301 ± 27 vs 117± 15
Novel Cell Encapsulation Formulation

Protects Allotransplanted Islets Long-Term with No Immunosuppression

Claims include:

- Barium-gelled alginate compositions
- Encapsulated cells

Methods of:
- delivering biomolecules
- coadministration with immunosuppressants
- reducing immunoreactivity of a host
Microlslet, Inc. (San Diego, CA)
- Microlslet-P™
- Completion of pre-clinical studies in expected in 2006; NDA filing in 2011

Amcyte, Inc. (Santa Monica, CA)
- Encapsulated Proliferating Islets™
- Currently in Phase I/IIa clinical trials

Living Cell Technologies (Australia)
- DiabeCell™
- Application to begin clinical trials in NZ submitted August, 2006
# Next Steps

## Short Term:
- Primate studies
  - Allograft transplantation in rhesus monkeys without immunosuppression
- Better understanding of mechanism
- Comparative studies with other formulations

## Long Term:
- Applicable to other cell types?
  - genetically engineered cells, embryonic stem cells, myocardial cells, etc.