



Ximerex, Inc.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health



National Institutes of Health Commercialization Assistance Program
(NIH-CAP)

Company Profile

Industry Sector: Biotechnology – Regenerative Medicine/Transplantation

Company Overview: Ximerex (pronounced KI'-mer-ex) is an early stage company developing innovative and proprietary technology that provides cells, tissues, and organs from donor pigs for transplantation. Our technology makes the transplantation safe, feasible, and cost effective. The technology prevents rejection while minimizing and even eliminating the need for anti-rejection drugs. Other innovations include eliminating PERV (porcine endogenous retrovirus) from pigs and humanizing pig livers by growing human cells in genomically modified pigs.

Target Market(s): There is a huge unmet need in transplantation medicine. Most patients who need a transplant never receive one. The four major categories include pancreatic islets for type 1 diabetes, as well as hearts, kidneys, and livers for end stage organ failure. The market in the developed world is estimated at \$65 billion per year.

Management

Leadership:

William E. Beschorner, M.D., President and Chief Scientific Officer, has more than 30 years research experience in bone marrow transplantation and xenotransplantation. Prior to founding Ximerex, Inc., he was an experimental immunopathologist at the Johns Hopkins Hospital, solving clinical challenges in transplantation. He has more than 130 publications and 5 patents and patent applications.

Advisors:

Kelly F. Lechtenberg, DVM, PhD, at MVS, Inc. Oakland, NE – swine technology and management
Randall Prather, PhD, Univ. Missouri, Columbia, MO – transgenic pigs
Richard Kruger, Ph.D., Mansfield, MA – Liaison with FDA for xeno, cell tx
Yasuhiro Takeuchi, Ph.D., University College, London, UK – co-discoverer of PERV
Louis M. Scarmoutzos, Ph.D., MVS Solutions, Inc., Boston, MA – business advisor

Key Value Drivers

Technology: Human cells are grown within fetal pigs destined to be transplant donors of cells, tissues, and organs. This accomplishes the major goals of transplantation within the pig rather than the patient – 1) production of human T regulatory cells to prevent rejection; 2) accommodation of pig tissues to resist antibodies; and 3) hybrid human/pig tissues with more human like function.

Competitive Advantage: The safety and effectiveness of transplantation is substantially improved by accomplishing the goals of transplantation outside of the patient, before transplantation. The risk to the patient is accordingly reduced. Pigs can provide the transplants needed in a cost effective manner.

Intellectual Property: Patents, trade secrets, proof of principle in large animals, including pig islet tissue into diabetic monkeys, transgenic pigs, PERV free pigs. Strategy: Completion of the preclinical research and development, FDA allowance for phase I/II trials and acquisition/partnership with a large biomedical company.

*Technology funded by the NIH (NIAID, NIDDK, NHLBI), and commercialized under the NIH-CAP, the JDRF, and NIST, Department of Commerce.

Product Pipeline

1. Transplantation kit: Pig cells, tissues, or organs for transplantation and the corresponding specific T regulatory cells programmed to provide acceptance of the pig transplant without anti-rejection drugs.
 - a. Pancreatic islet tissue for curative treatment of type 1 diabetes.
 - b. Hearts for end stage heart failure.
 - c. Kidneys for end stage kidney failure.
 - d. Livers, including humanized livers, for liver failure.
2. Pigs with humanized livers for research and development, such as new vaccines and therapies for hepatitis C. Currently, chimpanzees are the only animals other than humans that can be infected with hepatitis C.
3. Production of high grade swine tissues for research and development and for clinical transplantation.
 - Herd of ultraclean defined pathogen free VitalPure™ pigs for clinical xenotransplantation. PERV is being eliminated from this herd.