



Generex BIOTECHNOLOGY™

Forward Looking Statements

During the course of this presentation, it is possible that statements that could be construed as forward-looking statements within the meaning of federal securities laws and regulations may be made. The eventual outcomes of our various research and development activities could differ substantially from those anticipated in any forward-looking statements made today. You should not rely on any forward-looking statements and you should consider any such statements in light of the cautionary statements that are set forth from time to time in our filings with the Securities and Exchange Commission.

During the course of this presentation, data from certain clinical studies may be shown. These studies were sponsored independently by Generex.

The Company Assumes no obligation to update the information contained in this presentation.

Company Profile

- Focused on the development and commercialization of innovative treatments for diabetes, cancer and infectious diseases
- Validated technology platforms in RapidMist™ (buccal drug delivery) and first-in-class active immunotherapies
- Flagship drug Generex Oral-lyn™, an oral insulin spray
- Antigen Express subsidiary having a robust drug pipeline including a late-phase II breast cancer drug
- Significant additions to the management team and scientific advisory board
- Strong global relationships and patent portfolio

Management Team

- Mark Fletcher, President and CEO
- Dr. David Brusegard, COO
- Stephen Fellows, Acting CFO
- Dr. Gerald Bernstein, M.D., VP, Medical Affairs
- Dr. James H. Anderson, Jr., M.D., Senior Scientific Advisor
- Dr. Jaime Davidson, M.D., Medical Director
- Dr. Eric Von Hofe, PhD, President of Antigen Express

Reorganization

- Reorganization was imperative because of what we have learned about Type 2 and Type 1 Diabetes Mellitus and the conditions known as Pre-Diabetes or Impaired Glucose Tolerance
- Imperative because of what we have learned about the differences between the very rapid absorption of insulin into the abundant blood vessels of the lining of the mouth and throat compared to the much slower absorption of insulin injected under the skin
- Imperative to add shareholder value by expanding the portfolio of diabetes care pharmaceuticals
- Imperative to expand beyond diabetes and insulin

About Dr. James H. Anderson

- James H. Anderson, Jr., MD, FFPM, FACE
- Physician, Internal Medicine, Endocrinology and Metabolism
- Active in Diabetes research for last 42 years
- 25 years of insulin and diabetes drug development at Eli Lilly
- Medical / Scientific Advisory Board of Generex Biotechnology

Pathways

- These are the exciting pathways that our learning has opened for us:
 - ✓ Generex Oral-lyn™
 - ✓ Amaranthus Biosciences
 - ✓ Antigen Express
 - ✓ Future opportunities

Generex Oral-lyn™

- FDA letter, response and plan
- Current Trials
- Clinical Plan for Registration in Major Markets

FDA

- No safety issues identified in trials
- No safety questions raised by FDA
- No device concerns from FDA
- As is normal, there were questions about pre-clinical, clinical, toxicology, manufacturing, and regulatory and product labeling
- Historically, wide variety of formulations and changes were made

Our past provides a learning experience

*Now we are moving forward to the head of the line, past
Mankind and others because of what we know*

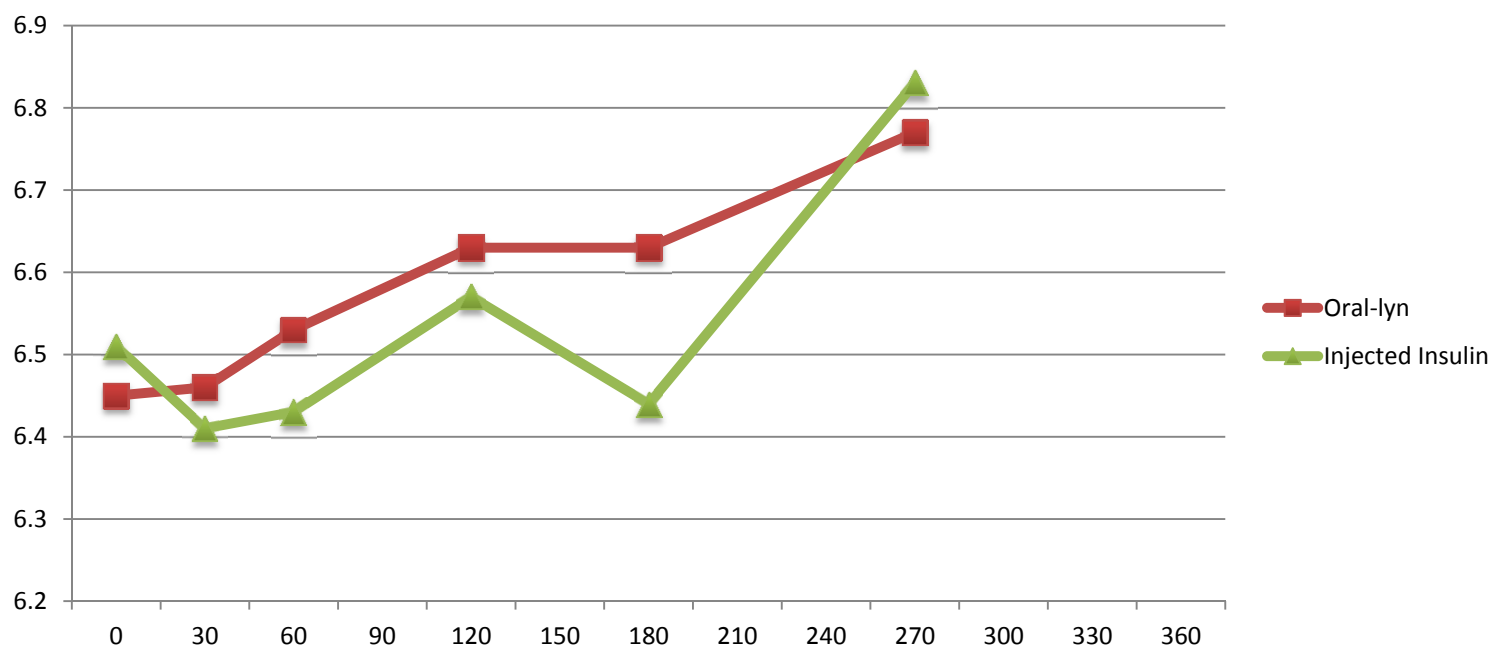
- The FDA GUIDANCE placed NO LIMITATIONS OR RESTRICTIONS on the types of patients included or trial designs of our current and future planned clinical studies

Current Clinical Trials

- 084 - Closing trial to achieve final data analysis to guide future clinical plans and development of data package for FDA
- Prevorol
- India
- Treatment IND

Equivalent HbA1c Control

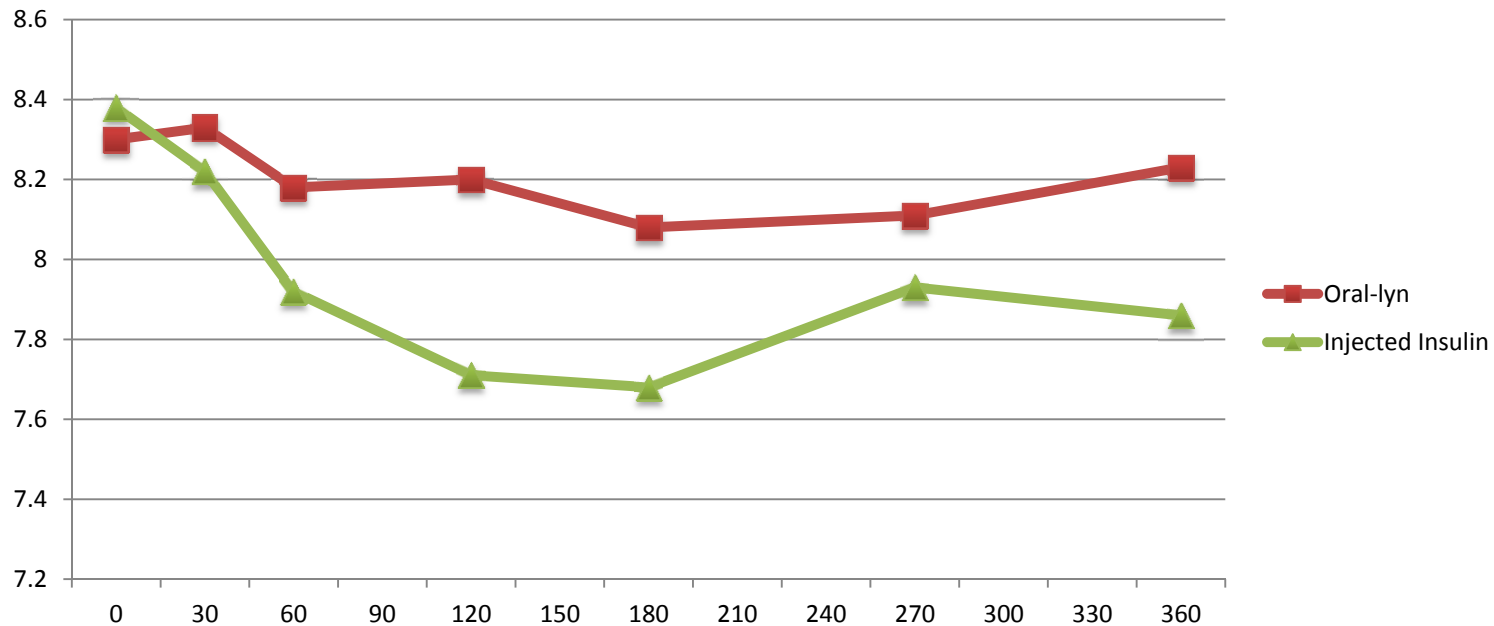
Well Controlled Type 1 Patients in Trial 084 (Interim Data)



Patients with baseline HbA1c of < 7.0 %
Injection patients switched to Oral-lyn at 180 days
Oral-lyn patients remained on Oral-lyn

Equivalent HbA1c Control

Poorly Controlled Type 1 Patients in Trial 084 (Interim Data)



Patients with baseline HbA1c of > 8.0 %
Injection patients switched to Oral-lyn at 180 days
Oral-lyn patients remained on Oral-lyn

Current Clinical Trials

- 084 - Closing trial to achieve final data analysis to guide future clinical plans
- Prevoral – Results in obese patients with IGT demonstrated rapid rise in insulin at 30 minutes and reduction of post meal blood glucose at 120 and 180 minutes with no hypoglycemia
- India
- Treatment IND

Expanding focus on Generex Oral-lyn™

- Not just an alternative to the needle for type 1 and type 2
- Potential for delaying or preventing development of diabetes
- Ability to achieve metabolic benefits that cannot be achieved with subcutaneously injected insulin (prolonged reduction of overproduction of glucose by the liver)
- Rapid absorption with sharp peak mimics normal insulin secretion
- Short duration of activity reduces potential for hypoglycemia
- No lung problems

Clinical Program

- Rapid registration in targeted Major Markets is primary goal
 1. Key activity / effect (pharmacokinetic/glucodynamic) study with final formulation
 2. Series of small, well designed Phase 3 studies (potentially conducted as one study with multiple arms)
- Consensus meeting with FDA to obtain agreement with clinical plan and data package to insure timely regulatory agency review and marketing approval
- Additional added-value market expansion work will be done concurrently

Amarantus Biosciences

- Leading research center in Parkinson's disease licensed Generex RapidMist drug delivery system for delivery of peptide drug molecules
- Diabetes occurs when the insulin producing beta cells die (apoptosis)
- MANF peptides produced in pancreas may provide a very early indication (*biomarker*) of cell injury allowing early treatment to prevent further beta cell injury
- MANF family of peptides may slow or block beta cell death resulting in delay or prevention of developing clinical diabetes (and reduction in complications)

Generex-Amarantus Synergy

- NIH and JDRF have conducted prevention trials using small doses of injected insulin to block the immune system, but had no specific, early way to determine who was really at risk of developing type 1 diabetes, and could only guess whom to treat in the clinical trials
- MANF biomarker may identify the right people to treat at earliest stage of the development of diabetes
- **Generex Oral-lyn™** may be the right (and *best*) way to deliver the small amounts of insulin needed to block the immunologic destruction of the beta cells in otherwise healthy children without causing hypoglycemia

Antigen Express

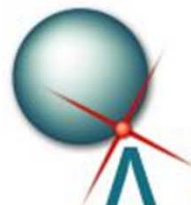
Type 1 and type 2 diabetes both have strong components of immunologic abnormalities.

The research work of Antigen Express in the field of immunology has developed a methodology for significantly increasing the potency of specific peptides to detect autoimmune T cells in the blood of patients with type 1 diabetes.

This technology holds tremendous potential for synergies across the two companies to discover and develop immunological tools and therapies to benefit diabetes

Our Objectives Going Forward

- Objectives to create robust product portfolio with scientific evidence of clear potential for adding significant value through producing short-term, medium-term and long-term income coupled with strong future growth
- Advancing Generex Oral-lyn™ clinical and commercialization programs
- Leveraging RapidMist drug delivery platform and unlocking its value by delivering new drugs, new proteins, and new enzymes for better treatment of diabetes and other diseases
- Expanding product portfolio of innovative therapies for prevention and treatment of diabetes and its complications
- Achieving sound collaborations, alliances and acquisitions



ANTIGEN EXPRESS, INC.

A division of  **Generex** BIOTECHNOLOGY

Experienced Leadership

- Eric von Hofe, Ph.D., President
- Minzhen Xu, M.D., Ph.D., Vice President, Biology
- Douglas Powell, Ph.D., Director of Immunobiology
- Nikoletta Kallinteris, M.S., Project Leader

Key Scientific Advisors

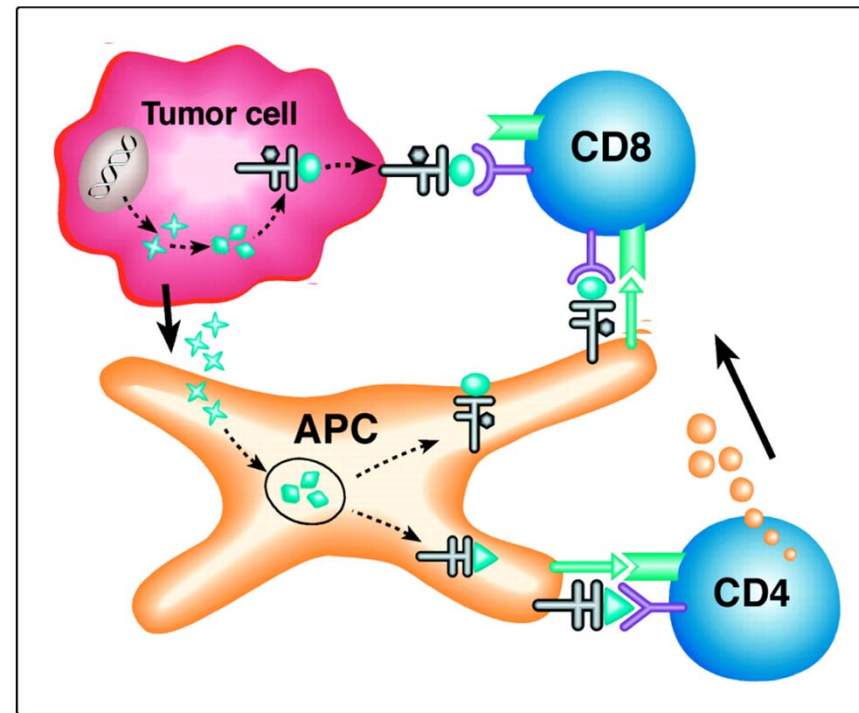
- Dr. Craig Eagle
 - Senior Director, Global Oncology, Pfizer Global Pharmaceuticals.
- George E. Peoples, Jr., M.D., F.A.C.S.
 - Chief of Surgical Oncology at Brooke Army Medical Center at Ft Sam Houston in San Antonio, TX, a Professor of Surgery and the Director & Principal Investigator of the Cancer Vaccine Development Program at Uniformed Services University of the Health Sciences in Bethesda, MD, and the Deputy Director of the United States Military Cancer Institute. Dr. Peoples is a graduate of Johns Hopkins University School of Medicine.

Antigen Express Mission

- ❖ Develop 'next generation' immunotherapeutic and prophylactic vaccines
 - *Self-potentiating*
 - *Fully synthetic*
 - *Off-the-shelf*
- ❖ Target products to major unmet medical needs (e.g., breast and prostate cancer)
- ❖ Leverage technology platform for diagnostics and clinical immune monitoring

CD4+ T Cells Are Critical Mediators

- Antigen presenting cells require CD4+ T cells for effective CD8+ T cell activation (cross-priming)
- CD4+ T cells provide cytokine help for CD8+ T cell activity
- Leads to more robust stimulation of CD8+ cytotoxic T lymphocytes, epitope spreading for more broad anti-tumor immunity, and immunological memory



Journal of Clinical Oncology, Vol 17, Issue 3 (March), 1999: 1047

Oncology Pipeline

Product	Disease	Preclinical	Ph 1	Ph 2	Ph 3	
AE37	<i>Her-2/neu+ breast cancer</i>					
AE37	<i>Her-2/neu+ prostate cancer</i>					
AE37/ GP2	<i>Combination</i>					
AE08	<i>Melanoma</i>					
AEH10p	<i>HPV (cervical)</i>					

Infectious Disease Pipeline

Product	Disease	Preclinical	Ph 1	Ph 2	Ph 3
AE443p	<i>Avian Influenza (H5N1)</i>				
AEA35p	<i>Swine Flu (H1N1)</i>				
AE298p	<i>HIV</i>				

AE37

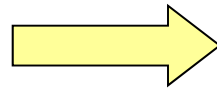
***A First-in-class Self-potentiating
Active Immunotherapy for Cancer***

Antigen Express 2010 - 2011 Theme

AE37

❖ **Biotech Mindset**

- ✓ High efficiency
- ✓ Low cost
- ✓ Calculated risk
- ✓ High goals
- ✓ Good, exciting science



❖ **Pharma Industry Mindset**

- ✓ Exceed FDA requirements
- ✓ Generous trial sizes
- ✓ Conservative approach
- ✓ Clear path forward
- ✓ Good, solid science

AE37 Positioning

Positioned as adjuvant therapy for
HER2 1+, HER2 2+ and HER2 3+ breast cancer

AE37 Addresses Unmet Need
& Expands Treatment Options

Herceptin - \$5.96B in sales (2010)
Tykerb - \$189M in sales (2008)

25%



HER2 0
25%



HER2 1+



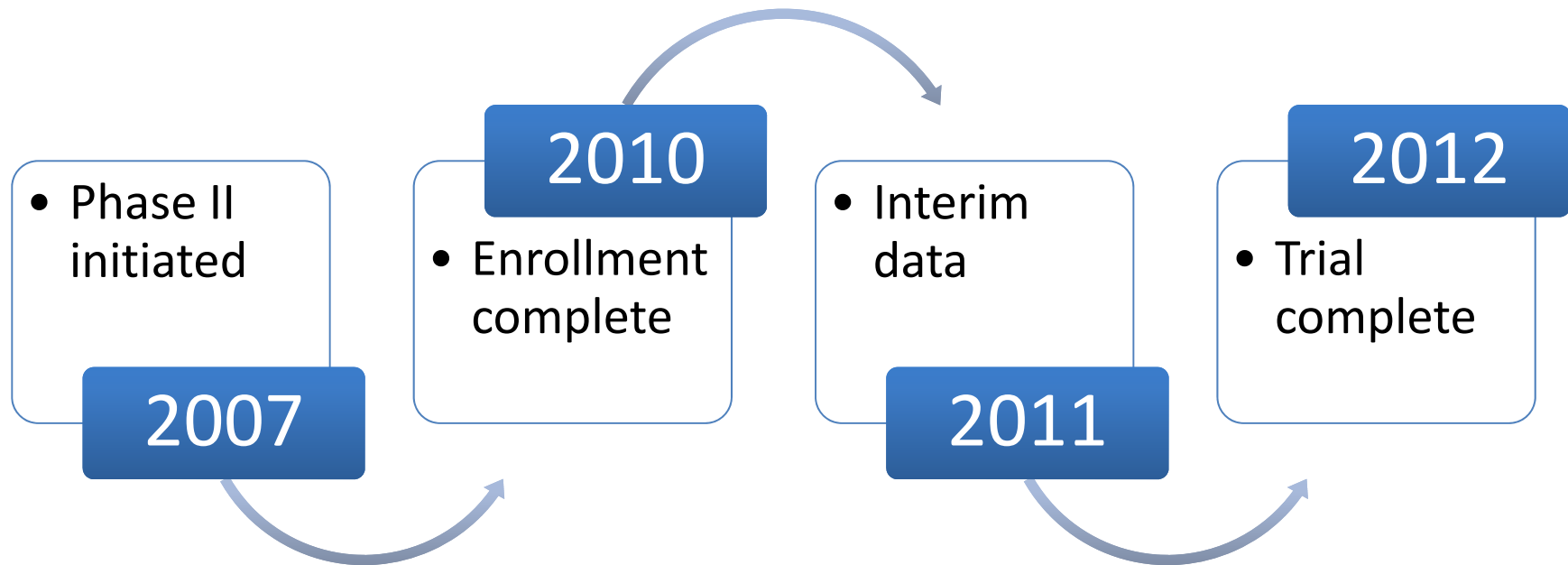
HER2 2+



HER2 3+

AE37 - > \$1B opportunity!

AE37 Phase II Trial Milestones



Development Strategy

- Statistical modeling of ongoing Phase II breast cancer trial
 - Predict likely endpoint using interim data and event-driven adaptive design versus landmark analysis
- Phase III breast cancer trial
 - HER2 1+ and 2+ patients with node-positive or high risk node-negative breast cancer
 - 1000 patients: US, Europe, China, Japan (leverage existing sites)
 - Randomized, controlled, double-blind study under a Special Protocol Assessment
 - Finalizing discussions for manufacture of final product

Development Strategy

- Phase II prostate cancer trial
 - Protocol established, newly diagnosed metastatic patients
 - 250 patients in the US, Canada and EU
 - Randomized, controlled, single blind study

Summary of AE37 Clinical Trials

- Phase II Breast Cancer Trial
 - Early data shows <50% fewer relapses in AE37 arm
 - Very good safety and immunological response
- Phase I Prostate Cancer Trial
 - Similar safety and immunological response
 - Demonstrated immunological response to boosting
 - Protocol for Phase II established
- Combination Phase I Trial (AE37 & GP2)
 - Safety of peptide combination demonstrated

Upcoming Catalysts

Milestone	Date
AACR – Dr. George Peoples Abstract of AE37	Q2 '11
ImVacS – Program and Technology update	Q3 '11
AE37 Phase II Interim Results (200 patients completed)	Q3 '11
SABCC Presentation of AE37 clinical results	Q4 '11
Prostate cancer Phase II begins (250 patients)	Q4 '11
Potential Partner Agreement	Q4 '11
Initiate Phase III AE37 for breast cancer	Q1 '12

Spin-Out Plans

- Generex intends to spin-out Antigen Express, Inc. as a separate DTC-eligible SEC registered company
- Following the spin-out, Antigen Express will seek to list its common stock on a national stock exchange
- Spin-out will be accomplished by the issuance of one or more dividends of Antigen Express stock to Generex stockholders
- Following the issuance of stock dividends, Generex expects to retain a controlling interest in Antigen Express