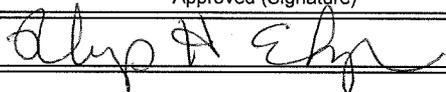


*Animal*

| U.S. Department of Agriculture<br><b>Accomplishments Report AD-421</b><br>U.S. Dept. of Agriculture, State Agricultural Experiment Stations and Other Institutions   |  |   | Date (Month, Day, Year)           |
|--|--|---|-----------------------------------|
| 1. Accession<br>0225192  | Agency Identification No.<br>2. SAES 3. LA.B | 5. Work Unit/Project No.<br><b>LAB04088</b>               | 6. Status<br><b>Annual Report</b> |
| 7. Title<br>DNA Delivery Platforms: Increasing Expression of Pharmaceutical Proteins and Delivering DNA for Expression of Therapeutic Proteins   |  |   |                                   |
| 12. Investigator Name(s) (Last Name and Initials)<br>Cooper, R. K.   |  |   |                                   |
| 20. Termination Date 09/30/2015  |  | 40. Period Covered (mo/da/year): 01/01/2011 TO 12/31/2011 |                                   |
| Outputs:<br>Results from this project have been provided to numerous groups throughout Louisiana to inform citizens, local, and state leaders. Our project promotes Baton Rouge in the biotech arena and impacts the pharmaceutical industry by lowering drug prices through innovative approaches. In addition, research progress was shared with TransGenRX business collaborators including Esperion Therapeutics, Swiftwater Consulting Group, and Cleveland Clinic's Cardiology Department.   |  |   |                                   |
| Outcomes/Impacts:<br>DNA delivery platforms that greatly expedite the clone production process for cells producing therapeutic proteins is under investigation. By coupling technology with modern bioreactors, significant cost savings can be obtained over traditional manufacturing methods. Collaborations between TransGenRx and our lab has resulted in TransGenRx's ability to meet with FDA representatives and begin establishing pathways for approval of our biosimilars in the U.S. market. Our objectives have resulted in a series of experimental goals. Our first goal was to determine if the transposon vector coupled with an avian cell line is capable of producing fully functional monoclonal antibodies and other proteins. TransGenRx used our technology and entered into a commercial contract with Esperion to produce a biopharmaceutical protein to treat atherosclerosis. TransGenRx has completed the first contract and is pursuing another contract with Esperion within the first quarter of 2012. The second goal of analyzing spent media from avian cell culture to develop a media that will allow for protein expression in hollow fiber systems is still underway. This research has also opened the door for media optimization of another production platform, Hyperstacks from Corning, which could potentially reduce production cost and enhance protein expression. The third goal compares our current transposon-based system with two new transposon vectors to increase insertion efficiency and the ability to overcome silencing. Success with this endeavor has led to evaluating other chromosome insertion systems to further increase our number of incorporation sites. |  |   |                                   |
| Publications:<br>Gene Therapy Using Transposon-based Vectors. R.K. Cooper. Issued 10/11/ 2011. US Patent # 10/ 582,812 Canadian Patent Application No. 2,490,693 entitled: Gene Regulation in Transgenic Animals Using a Transposon-Based Vector. Our File: 56187-309181 (0101CA) Canadian Patent No. 2,490,693  |  |   |                                   |
| Participants:<br>R. Cooper (PI), and F.O. McManus, LSU AgCenter.   |  |   |                                   |
| Target Audiences:<br>International and National Scientific communities.  |  |   |                                   |
| Project Modifications:<br>Nothing significant to report during this reporting period.  |  |   |                                   |
| Approved (Signature)   |  | Title   | Date                              |
|   |  |   | 3-23-12                           |