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## **Summary**

- Atherosclerosis is a chronic disease characterized by vascular inflammation and compromised function of large and medium sized arteries. It is the major cause of myocardial infarction, stroke, and peripheral artery disease.
- Princeton-based CardioVax is developing a vaccine to ameliorate/prevent atherosclerotic cardiovascular diseases
- CardioVax holds an exclusive worldwide license to technologies in the field of active immunization discovered through collaborations between Professor Jan Nilsson, Lund University Hospital, Malmö, (LUHM) and Professor PK Shah, Cedars-Sinai Medical Center (CSMC), Los Angeles, CA.
- Drs. Nilsson and Shah identified an athero-protective immune response against epitopes in oxidized low-density lipoprotein (oxLDL). They developed a vaccine comprised of specific immunogenic peptide fragments of apolipoprotein B-100 conjugated to a carrier molecule and formulated with an adjuvant.
- CardioVax' lead vaccine (CVX-210-H) has demonstrated greater than 60% reduction in atherosclerotic lesions in treated animals compared to controls. Non-clinical safety and pharmacology studies are in progress.

## **Unmet Medical Need**

- In the US alone, more than 80 million adults have some form of atherosclerotic cardiovascular disease (CVD). CVD is noted as the underlying cause for over 35% of all deaths in the US.
- CVD costs the US economy in excess of \$400 billion annually.
- The global cardiovascular pharmaceutical market is forecast to be \$116.3 billion in 2010.
- Use of the best available medical and surgical treatments has only managed to reduce the burden of CVD by approximately 30%, leaving an unmet medical need of nearly 70%.
- CVX-210-H is intended to be used in conjunction with these other therapies so as to offer effective treatment and possible prevention to the entire population.

## **Management Team**

Oye Olukotun, MD, MPH, FACC, FAHA – Chief Executive Officer

Cardiologist and industry veteran with more than 30 years of experience in big pharma (Mallinckrodt, Bristol-Myers Squibb) and biotech start-ups (VIA Pharmaceuticals, Co-founder & CMO; AtheroChem, Advising CMO; Esperion Therapeutics, CMO).

Mark Carvlin, PhD – Chief Operating Officer

Physicist and drug developer with more than 25 years of experience in big pharma (Bristol-Myers Squibb) and biotech start-ups (NanoScan Imaging, CSO; VIA Pharmaceuticals, Consultant; AtheroChem, COO; Esperion Therapeutics, Consultant).

Janice Rae Mitrovich – Executive Director

Project manager and planner with more than 23 years of diverse experience from the pharmaceutical (Bracco Group, GPC Biotech), biotechnology (Cytogen, Bio-Imaging Technologies), and contract research industries (IBRD-Rostrum Global).

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### **Funding/Phases of Development**

- CardioVax is privately held and has raised sufficient capital to fund development through IND submission (Q1 2010) and Phase 1a (Q2 2010- Q2 2011)
- The company will raise additional capital or seek a strategic partnership to fund clinical development (Phases 2 and 3) through submission of the NDA

### **Intellectual Property**

- Patents issued in the US, Europe (22 countries), Australia, and Russia
  - US 7,527,795
  - US 7,528,225
  - US 7,544,360
  - US 7,556,811
- Additional patents pending in North America, Europe, and Asia

### **Competitive Landscape**

- At present, CardioVax is the only company pursuing active immunization (vaccine-based). Roche/Genentech is collaborating with BioInvent to develop passive immunization (antibody-based).
- CardioVax' vaccine is will be administered multiple times during a person's lifetime, an initial immunization followed by periodic repeat boosters; BioInvent's antibody will be administered as a single course of therapy during an acute intervention.

### **Contact Information**

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### **Selected Publications**

A more extensive selection of publications is available at [www.cardiovox.com/resources](http://www.cardiovox.com/resources).

1. Shah PK, Chyu KY, Fredrikson GN, Nilsson J. Immunomodulation of Atherosclerosis with a Vaccine. *Nature Clinical Practice Cardiovascular Medicine*, Dec 2005;2(12):639-646.
2. Hansson G, Nilsson J. Vaccination against atherosclerosis? Induction of athero-protective immunity. *Semin Immunopathol* 26 May 2009 (published online).
3. Nilsson J, Hansson G. Autoimmunity in Atherosclerosis: A Protective Response Losing Control? *J of Intern Med* 2008; 263:464-478.
4. Sjögren P, Fredrikson GN, Samnegard A, Ericsson CG, Ohrvik J, Fisher R, Nilsson J, Hamsten A. High Plasma Concentrations of Autoantibodies against Native Peptide 210 of ApoB-100 are Related to Less Coronary Atherosclerosis and Lower Risk of Myocardial Infarction. *Eur Heart J* 2008; 29:2218-2226.
5. Nilsson J, Hansson G, Shah PK. Immunomodulation of Atherosclerosis: Implications for Vaccine Development. *Arterioscler Thromb Vasc Biol*. 2005;25:18-28.
6. Chyu KY, Zhao X, Reyes O, Babbidge S, Dimayuga P, Yano J, Cercek B, Fredrikson GN, Nilsson J, Shah PK. Immunization Using an Apo B-100 Related Epitope Reduces Atherosclerosis and Plaque Inflammation in Hypercholesterolemic Apo E (-/-) Mice. *BBRC* 338 (2005) 1982-1989.