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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:** Pharmaceuticals

### Company Overview:

Auxagen, Inc. was established in 2004 to develop agents to treat wounds and tissue fibrosis which currently lack effective therapy. Its scientists developed novel TGF- $\beta$  receptor antagonist products which have potent TGF- $\beta$  antagonist activity and growth promoting effects on epithelial and endothelial cells. These products are effective in enhancing wound healing and reducing scarring by topical administration and in ameliorating and reversing lung fibrosis by intranasal administration in relevant animal models. These products are currently in preclinical trials. An ongoing SBIR phase II study on wound treatment is expected to result in an IND filing in 2012. A SBIR phase I study on lung fibrosis has been completed.

**Target Markets:** Complicated skin wounds and various chronic skin wounds, aging skins and conditions featuring tissue fibrosis (e.g., lung fibrosis, liver cirrhosis and fibrosis of other tissues).

**Opportunity:** Auxagen is currently seeking partners and licensees to develop the TGF- $\beta$  receptor antagonists into commercial products.

## Key Value Drivers

**Technology:** Auxagen's TGF- $\beta$  antagonists are the first and only known TGF- $\beta$  receptor antagonists developed anywhere. They block TGF- $\beta$  binding to TGF- $\beta$  receptors in cells and tissues. Auxagen's TGF- $\beta$  antagonists are effective in enhancing dermal wound healing and reducing scarring, and in ameliorating lung and liver fibrosis in animal disease models. They have great potential in treating human diseases.

**Competitive Advantage:** Auxagen's products act rapidly and have both TGF- $\beta$  antagonist activity and novel epithelial/endothelial cell growth promoting activity. In contrast, other TGF- $\beta$  antagonists such as TGF- $\beta$ -binding proteins (e.g., TGF- $\beta$  antibodies) do not have such properties. Auxagen has the exclusive right of intellectual properties of the TGF- $\beta$  antagonists.

**Plan & Strategies:** Auxagen plans to complete SBIR phase II studies on wound treatment and file an IND in 2012. The strategies for clinical trials and commercialization of the TGF- $\beta$  antagonists are to seek partnerships with large pharmaceutical/biotech companies and/or investors for clinical trials.

\*Technology funded by the NIH and being commercialized under the NIH-CAP

## Management

### Leadership:

Shuan S. Huang, Ph.D. President and Research Director- >25 years of TGF- $\beta$  structure and function research, identification of an important receptor-binding site in the TGF- $\beta$  molecule and development of the first synthetic TGF- $\beta$  receptor antagonists

Michael W. Huang, B.S. in business, CEO- ~10 years of experience in the management of businesses

### Scientific Advisory Board:

Jung S. Huang, Ph.D., Professor, St. Louis University- one of the pioneers in growth factor research (PDGF, aFGF and TGF- $\beta$ )

Frank E. Johnson, M.D. Professor of Surgery, St. Louis University- an expert in cutaneous wound treatment

Robert M. Senior, M.D., Professor, Washington University- an expert in pulmonary fibrosis research and treatment

## Product Pipeline

The prototype TGF- $\beta$  receptor antagonists have limited solubility in aqueous solution and short plasma half-lives. Our newly developed derivatives have excellent solubility in aqueous solution, ~10-20-times more potent TGF- $\beta$  receptor antagonist activity and longer plasma half-lives than those of the prototype antagonists. These new products are effective in enhancing dermal wound healing and reducing scarring, and in ameliorating (or even reversing) lung and liver fibrosis in standard animal disease models. They do not show adverse effects in treated animals. These products (gel formulation for wound treatment and aerosol formulation for lung fibrosis treatment) are currently in preclinical trials. Parenteral administration treatment of liver fibrosis will be the next Auxagen target. Tissue-specific targeting (e.g., liver, kidney and pancreas) technologies of TGF- $\beta$  receptor antagonists are Auxagen's future targets.