

# *Evaluation of Squalestatin 1 as an Enzyme Inhibitor for Lowering Cholesterol*

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## **Executive Summary**

The objective of this project is to determine the feasibility of manufacturing and commercialization of a novel enzyme inhibitor of cholesterol synthesis. The goal is to propose a drug capable of lowering at least 50% of the total cholesterol level in patients dealing with high serum levels with the highest efficacy. This was done by analyzing the FDA and manufacturing processes, equipment pricing, manufacturing prices and determining highest demand for the drug, therefore, determining the best price for the drug.

The suggested drug inhibits an enzyme in biosynthesis of cholesterol but is differentiated from statin drugs by its higher efficacy and its area of operation. By working only as a squalene synthase inhibitor, squalestatin 1 (SQ1) does not decrease the production of coenzyme Q<sub>10</sub> (ubiquinone). Research has shown that this drug will lower serum cholesterol level by 50% using 10-20 mg/day dosage.

The success of this enterprise will mainly repose on the likelihood of its approval by the FDA and its marketing strategy. FDA process will be subdivided in four different phases with a specific goal at each step. Calculations evaluate the chances of SQ1 being endorsed by the FDA on its first attempt to reach 69%. Its overall duration is estimated at 10 years for a total cost of \$69.9 million.

To determine the best price for a unit of SQ1, four different prices were chosen; first, with \$1.33, second with \$1.7, third with \$4.8 and fourth with \$5.0 per unit. Best price for the drug was calculated using pricing analysis and demand model. The price was chosen based on the trends observed on the demand graphs. These graphs showed that lower prices give higher demand for the drug. The best price was determined to be \$1.33 per unit. This is lower than the generic brand of statin drugs in the market but based on the demand model and NPV graphs the demand will increase over years.

SQ1 is the product of a multi-stage process starting from the 48 hr fermentation of a fungus (*Phoma* sp.) and passing through series of separation systems such as column chromatography, centrifuge and packed bed column. Duration of the project is approximately 20 years and it takes into account the FDA approval process. TCI and FCI for this production are \$76 and \$77 million dollars with a manufacturing cost of \$271 million. Also, observed trends in NPV and ROI of 2% show that the project will be acceptable.