How to Win $800 Million on a Late Drug Entry

CASE STUDY – VELO1

Service:
Revise the Drug Development Portfolio. Recommend what to do with a specific candidate for drug development.

Client:
Large Pharmaceutical Company

Requirement:
Provide understanding of the drug development process and its nexus with Marketing Research and Competitive intelligence.

Situation:
A drug development company was faced with the clinical development candidate, potentially a very good antihypertensive drug that if developed would be the 7th drug on the market in its therapeutic class. The expected revenues, due to late entrance into the market, would be very low and it would not be cost-effective to allocate the significant amount of funds necessary to take it to the market. The company had an organizational structure that did not permit the implementation of efficient programs.

Scope:
Staffing: ten person weeks.
Deliverable: a drug development report including recommendations to reorganize the development infrastructure.

Discovery:
The team reviewed the cardiovascular market and determined that it would be very difficult for another compound of this class to gain a significant part of the market being number 7 on the market.

Considering the mechanism of action of the compound the team realized that a novel combination product could be developed. If such a compound could be found and licensed for the combination to add to the single entity product in question, the market of the product would be expanded and the cost of developing the single active ingredient would be shared with the novel combination. The new proposed drug development program would include the development of the single ingredient to market as a single entity, the traditional diuretic and the novel combination with a compound of a different class.
Semaphore advised the client that the investment to develop such a late entry into the market would not be profitable. If the Company wanted to be part of the antihypertensive armamentarium, a new type of product had to be created to successfully capture a significant piece of the market.

Outcome:
1. The decision was made to identify a licensing candidate as recommended.
2. The single entity recommended for the novel combination was found and in-licensed. On the basis of this recommendation a new 3-product development program was

planned by the client company and expeditiously implemented.
3. The program was cost-effectively completed and approval for the novel combination was granted by the FDA based on a single phase III international trial.
4. The novel combination was placed on the market with current sales greater than $800 million per year.