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## CAPITALIZATION OF INVESTING INTO MEDICAL DEVICE DEVELOPMENT ON THE HEALTH CARE MARKET

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Abstract:

Medical Device is a tool (product and application) intended to fill unmet needs of health care providers (customers) and their patients (consumers) on the health care markets. It means that the final capitalization of the medical device investment takes place during the trade between the producer/seller and the customer/consumer at the market.

Consequently, the investment into medical device development must be planned as a function of the number of units sold and the individual unit's price on the market plus the expected profit per unit. The other part of the equation is the presales cost. This cost includes, but is not limited to: (1) Manufacturing cost (idea, prototype, testing, product manufacturing), (2) Regulatory cost (approval for sales in individual countries), (3) Wholesale cost (warehouse, gross sales, brokering sales); (4) Export/import licenses, (5) Shipping and Handling, (6) Distributor's cost, (8) Customer's cost, (9) Taxes on production, marketing and sales, and (10) Market research and product marketing cost.

This is the Capital Cycle, a model for product capitalization which is the most profitable; but requires large investment into product development (R&D + Regulatory) and business infrastructure to carry-on marketing and sales. Only large companies may opt for this model.

Small businesses have two options: (1) Licensing Intellectual Property and (2) Selling (acquisition/merger) of the company. Both are the Capital Exit models, which can be applied at any time during the pre-sale product development process and both carry the same danger of negative consequences to the product and the intended goal to meet public needs. The benefits of this product could be lost or postponed. Fast money and early exits promoted by investors and/or shareholders could be the main reason why many potentially important medical devices never reached the market.

Usually the small business founders prefer licensing (Angel investors or corporate), and the small business companies regard the Early Exit Strategy as preferred solution for their investment (venture capital and corporate acquisition/merger). As the device development progresses, the small business founder find themselves in a chronic lack of cash and under pressure to make many compromises – some of which are causing delays of the development or change in the device design.

If accepted, this business strategy will be presented as power point presentation based upon a real success story of one diagnostically potent biomarker and the companies built around it to fund its pathway to the health care markets.