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***You have an idea! What next? Overview of how to create a successful
business plan with reference to the medical device industry***

**Masz pomysł! Co teraz? Sugestia jak stworzyć biznes plan sukcesu
w przemyśle medycznym**

In today's competitive environment it is not enough to just have a good idea for a business. What is important is knowing how to convey the idea and convince the right people of its feasibility. Unless you have sufficient capital to bring the idea to life without any external help, you need to know how to go after the necessary financing. Those are the venture capitalists that you need to present your idea to, and to do so, you need to write a business plan. Of course, there are probably hundreds of various formats available but there are some standard elements that need to be included in any business plan.

In this article I will identify the major parts of a business plan. All the elements will be described with reference to the medical device industry.

EVALUATE THE IDEA

Before you decide to write a business plan, you should ask yourself a number of questions: Is the idea feasible? Is it innovative? Am I willing to invest my own capital into the development of this idea? Do I have the right level of commitment? To have an idea does not mean to have an opportunity. What you have to keep in mind is that a start-up is a high risk operation and failure is a possibility, not a disgrace. It involves hard work and sacrifice.

With regard to the medical device business, it is especially important to evaluate the idea. Methods of evaluation, such as surveys or interviews, will help you determine the potential interest in your future product. Will there be demand for what you are trying to produce? You need to follow recent trends, and for example, in the medical device business they include:

- miniaturization
- intelligent devices
- design for consumer use
- minimally invasive
- biotechnology revolution
 - genomic, proteomics
 - biological medical devices
- new materials
- combination products
- disruptive technologies
 - that change how we do business
 - that change how medical devices deliver value

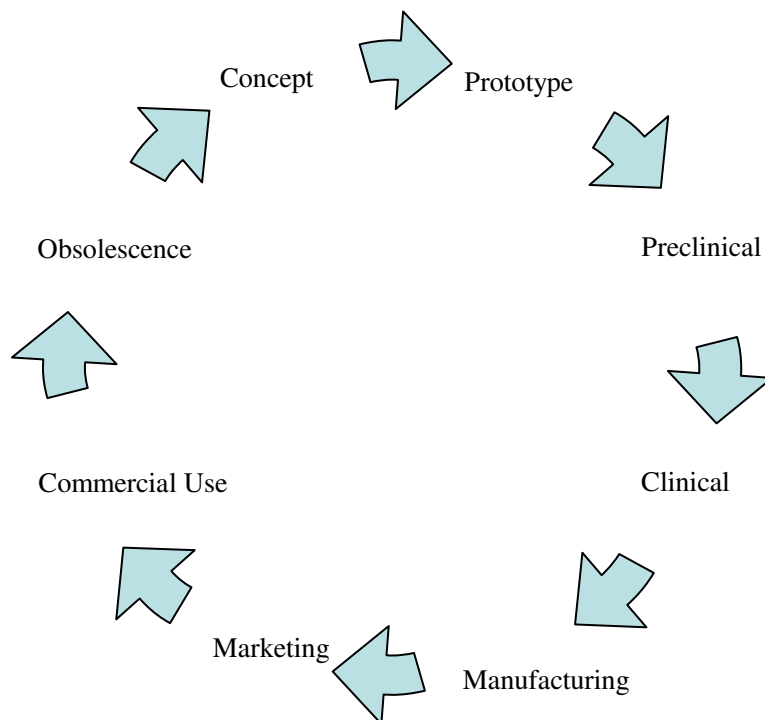
KNOW THE INDUSTRY AND THE MARKET

When putting together a business plan it is important that you know your industry. You have to analyze your competitors and their products. Ask yourself how can you will compete against them and what will make you better. What is it that you will offer that they have not offered?

For example, in the medical device industry, we can find the following growth areas:

- less invasive products
- less expensive products
- combining diagnostics and therapeutics in one setting; even including service, for example: including follow-up via telemonitorization
- patient perspective: restoring and maintaining comfort and quality of life
- BUT: Europe is spending less, which means that it is more difficult to sell innovative technologies at a high price

You need to have enough knowledge to be able to compete in the industry. It is crucial to know your product and that of your competitors. For example, in the medical device industry the Product Life Cycle is relatively short – approximately 2 years. The following phases are can be observed for this industry:



You have to research if there is demand for your product. Perform a market analysis and other widely used analyses such as S.W.O.T (Strengths, Weaknesses, Opportunities, and Threats) and Porter's Diamond. Research the latest trends, like the ones mentioned above, and also identify the market drivers. Will your product satisfy the current demand?

Recently identified market drivers for the medical device business include:

- Demography
 - aging population – increase of pathologies and multi-morbidity
 - cardiovascular
 - degenerative musculo-skeletal disease
 - neurological pathologies
 - lifestyle and environmental factor related disease
 - diabetes and obesity
 - cancers
- Technology
 - expansion of diagnosis and therapy
 - more pathologies are diagnosed earlier
 - more treatment options
 - minimally invasive therapeutics
 - control of healthcare expenditure
 - professional managers
 - public administration increasingly sensible to economical issues

BUILD A TEAM

If you plan to create a large company, you need to build a team. Lone wolves create perpetually small companies. Even before you put your idea into writing, you should surround yourself with people that you will collaborate with on creating the business plan and later, if successful, run the company with. You need to keep in mind that a good manager feels confident in hiring people better than herself/himself. Be conscious of your deficiencies and complement them with the best specialists. If you are not an expert in the industry, surround yourself with experts. To delegate means to let the expert do the job.

THE BUSINESS PLAN

1. Executive Summary

The Executive Summary introduces your company and your request. It should be no longer than two pages. It is recommended to write this page after you have completed the remainder of your business plan. Many people will only read the executive summary so it should entice your reader and encourage interest in your business.

The Executive Summary should outline:

- business name, address, and contact information
- brief description of your company including history (if applicable), industry and target market
- describe products and services and marketing mix you have designed to reach your customers
- summarize the research that you have performed
- explain how your company will succeed in the future
- brief description of management capabilities
- describe your funding requirements including how the money will be spent and repayment proposal

2. Business Concept and Product

In this part you will provide a business description and clearly define the problem that you are solving. Explain how the problem is being solved today and how your technology is differentiated from the currently available solutions. Make sure you explain your product, including customer needs and applications, and a synopsis of any underlying technology. This may include innovation, pricing strategies or customer service.

Other parts to be included:

- Intellectual property (especially important in the medical device industry):
Explain your plans to protect your intellectual property and other barriers to enter your space
- Legal form of your company:
Decide if your company will be a sole proprietorship, partnership or a corporation
- Owners:
List all shareholders including percentage ownership. Give a brief description of their position at the company or their area of expertise

3. Innovation and Technology

In this section you need to explain what pieces of technology you plan to implement. Describe the primary uses, benefits, and process steps involved. Describe the knowledge and abilities of the people within your company. Compare your current and new abilities with the competition and industry leaders.

In an industry, such as that of the medical devices where R&D is exceptionally relevant to the business, describe progress to date, plans, resources and highlight any technological advances or achievements. You should introduce the key technological trends and developments shaping your industry or product area and explain how are you responding to them. Indicate what technical expertise has been acquired by the business or is needed in the future. List all the qualifications and backgrounds of existing technical staff and external advisers or collaborators. You need to summarize R&D expenditure to date and specify future expenditure plans. Make sure you identify milestones or specific projects to be completed, and, where appropriate, provide short economic justifications for major projects.

To assure the understanding of your plan, keep technical details to the minimum and use footnotes to explain unusual terms when first introduced. Use simple drawings or flow diagrams to help describe any complex issues.

4. Market and Competition

In this section describe the market opportunity, including the size, history, characteristics, and dynamics of the market, showing how you fit in the market. Who will buy your product? You should provide an analysis of the target market including estimated size of the market.

Next step is to describe your competition. Every business has competition. Companies stating they have no competition lose credibility in the eyes of a lender. It is important that you identify the strengths and weaknesses of your main competitors. Depending on your industry you may want to provide a detailed assessment of your top 3-5 competitors; more if necessary.

- Primary competition
Identify your main competitors. Provide a detailed assessment including:
 - Summary of their product lines
 - How do their products compare to yours?
 - Strength of the competition and their sales estimates
 - Do they have the same target market or operate in your niche?
 - What are the company strengths and weaknesses including their products and services?
 - What is the impact on your company?
 - Why will people buy your product over the competition?
 - What makes your product different?
- Other competitors
Identify and provide a detailed assessment (similar to that completed for your primary competitor). Ensure you identify all other competitors and alternative services that customers may use instead of purchasing from you.

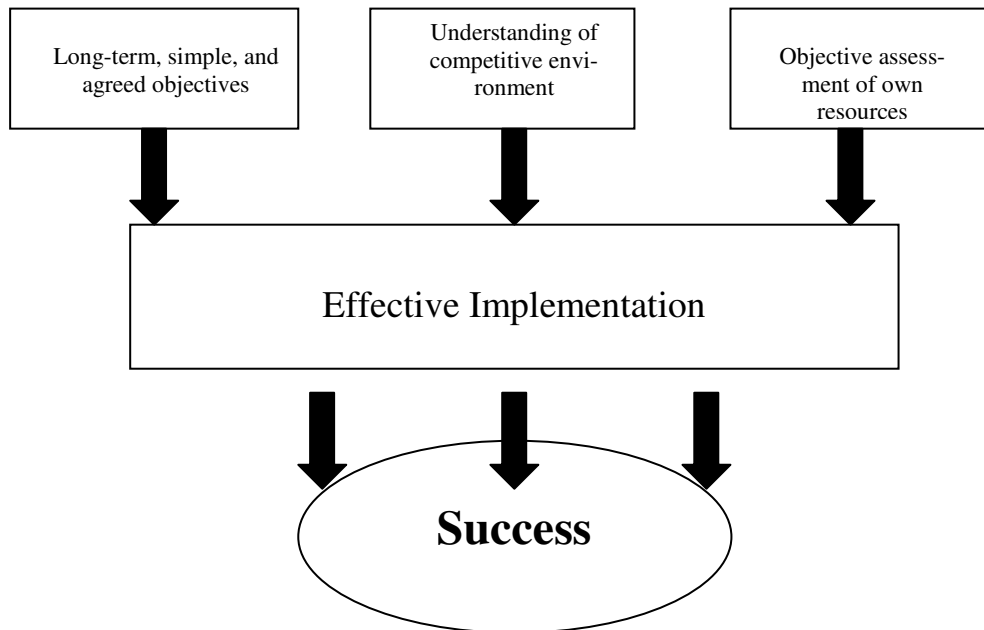
5. Strategy / Business Model

Describe your strategy and proposed business model. The strategy section of your business plan gives you (and your lender) a sense of your business direction. It provides focus on the long term goals and action plan. Make sure you present your short-term and long-term goals. Your goals should be specific, measurable and time specific. For example, if an objective is to maintain high customer

service, a measurable goal may include the number of returns in a given period. Ensure your short term objectives create a path to reach your long term goals.

Create an action plan. Describe the steps you have in place to achieve both your short term and long term goals. Include current processes and changes to be implemented. These may include changes to the management structure, sales force, location, delivery channels, pricing or quality control.

Elements of Successful Strategies



6. Sales and Marketing plan

In this section describe your marketing strategy, including a discussion on sales and distribution channels. Provide details on what market validation you have conducted.

Remember: “If you build it, they will come” does not work in today’s marketplace.

Explain how you will reach your target market. What message and media sources will you use? What image do you want to portray? Describe your strategy. A marketing plan includes more than just advertising. The most successful marketing campaigns incorporate a variety of methods to reach your market. Be innovative and creative with your strategy while maintaining a common theme and image of your company.

You may consider the following:

- traditional advertising medium: radio, television, magazines, newspapers
- internet advertising
- sales people: telemarketing, account managers
- trade shows, associations, cross marketing campaigns with your suppliers
- public relations: press releases, sponsorships, charitable donations

To present your marketing plan you may, for example, describe in detail 3-5 key marketing strategies. Show how each of these strategies enhances your image and attracts customers. Include costs, time lines, reach and expected return from each campaign. Outline the viability of the campaign including strengths and weaknesses of medium used.

7. Operations plan

In the operations plan cover all aspects of distribution, service provision, support, operations and/or manufacturing within this section. Depending on the nature and scale of your business, sub-sections could be used to handle key topics. Indicate the locations of the main premises and facilities. Describe plant/office/facilities and indicate sizes, capacities and utilization. Review recent significant capital expenditure and outline future plans. Include or append maps, charts, pictures etc.

If you decide to outsource any operating units or functions, present the necessary information and explain the process. With this you should include possible sub-contractors, cost and procedures of these operations.

8. Human Resources plan

List the founders and executive team, and provide their backgrounds, relevant experience. Provide a realistic assessment of management capabilities. Outline how your strengths will ensure you are able to implement company objectives. It is critical to identify possible weaknesses and strategies to overcome these weaknesses, such as outsourcing responsibilities, hiring a new person or independent consultants. Also provide a profile of your senior management including the president and owners. Outline responsibilities at the company, experience, education, ownership percentage, salaries and bonus structure.

Outline your staffing requirements in this section of your business plan, including a description of the specific skills that the people working for you will have to have. Present an organizational chart of your company and describe any departments you plan to create, including their functions. You also need to describe how you plan to find the staff your business needs, and how you are going to train them.

Next, determine how much salary each employee will be rewarded with, and total the cost of salary for all your employees. Discuss any benefits and retirement plans that each employee will receive.

9. Financial plan

One of the most important parts of the business plan is the financial plan. You should pay much attention to this part and be able to substantiate all the numbers presented. If you do not know the exact sums, you can estimate them based on industry averages and comparisons to other companies in the same line of business or base them on your market research. The following are the most important parts of a financial plan:

- **Income Statement**
It is recommended to prepare a quarterly income statement (profit & loss account) for a duration of 5 years. It should entail the company's projected revenues, gross margin, operating expenses (including depreciation), financial expenses (such as interest paid), taxes, and finally net income.
- **Balance Sheet**
It is a snapshot of your company's assets, liabilities, and owner's equity at a certain point in time. It is recommended to present a balance sheet for every end of your business cycle over the period of 5 years. Remember that a business cycle does not need to begin in January. You can select any time of the year but it should have a duration of twelve months. Also keep in mind that in any balance sheet:
$$\text{assets} = \text{liabilities} + \text{owner's equity}.$$
- **Statement of Cash Flows**
You should present monthly cash flow projections for the first year, or longer depending on the importance of cash flow and time needed for your business to become cash flow positive. Many readers of your plan - bankers, venture capitalists and other investors - will pay far more attention to the cash flow projections than to the income statements. They will seek to establish that the business will not run out of cash before it reaches profitability - more businesses fail due to lack of cash than for a negative income.

If you decide to finance your business solely by debt – a bank loan, you should design a loan repayment schedule. Will you retain all your earnings or begin repaying the loan as soon as your net income is positive? Also provide a financial proposal. Be specific when you outline how much money is required. Include uses for the funds, supplier quotes, proposed repayment terms, sources of repayment for the loan (cash flow) and collateral. Owners should have a clear understanding of their financial requirements including likely terms, conditions and other required supporting documentation. You are more likely to receive financing if you understand the lending process and make it easy for your banker to review your request. Provide a commentary on what you want to purchase and why. Show how the funds will benefit your company and prove that you are able to repay the loan. It is advisable to research different types of loans to understand the requirements and terms prior to meeting with an account manager at your bank.

It is also beneficial to perform basic financial ratio analysis. The more information and analyses you include in the financial plan, the better.

The table on the following page summarizes the expected return that investors will require in the medical device industry depending on the financing round and stage of the business.

Financing Round	Business Objectives	Expected Return
Seed	Product Research Market Research Preliminary Plan	75 – 100%
Start – up	Product Development In-Vitro / In-Vivo Proof Complete Management Team Confirm Market Size	50 – 75%
1st, 2nd, 3rd round	Clinical Trials + Selling Expand Work Force Manufacturing	30 – 50%
Mezzanine	Prepare for Initial Public Offering	25 – 30%
Public Offering	Market Development New Products	10 – 20%

10. Contingency Planning

A contingency plan should always be a part of your business plan, especially if you require external financing. All planning to invest in your company want to know what will happen with their share of the investment if your business fails. Here you should undertake a couple of scenario analysis.

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I would like to thank Mr. Michael Thiele for providing me with business related insights to the medical device industry.