ISCTE Business School
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BUSINESS PLAN: NANOLUNG

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Abstract

Lung cancer is the leading cause of cancer death, representing approximately 1.8 million diagnosed cases every year worldwide. The most aggressive form of lung cancer, SCLC (small cell lung cancer), is expected to be responsible to 10% to 15% of all lung cancer cases.

Nanolung, the solution proposed in this business plan, is a nanocarrier with three key functional components, that is able to distinguish between healthy and cancer cells, stop tumor progression and kill the cancer cells.

Recent trends suggest that well-established companies are more adequate to the activities regarding clinical trials and marketing drugs, while small companies, like Nanoplex, should explore niche areas with a strong science-based focus. Usually these two types of companies joint through mergers or acquisitions due to the technological star-ups financial difficulties pursuing to the market. Having said that, Nanoplex will make a license deal of the technology after phase two of clinical trials to a well-established pharmaceutical company.

The author conducted an analysis of secondary data like scientific articles, academic books and websites of relevant institutions for the subject under analysis, as well as, collected and analyzed primary data through semi-structured interviews with professionals with a vast experience in the pharmaceutical industry and particularly in the R&D areas, in order to validate the work contents.

This business plan allows to affirm that Nanolung, a treatment against SCLC, is economical and financial viable.

Keywords: Technological innovation, business model, startup company and small cell lung cancer treatment

JEL classification: M13, L65

Resumo

O cancro do pulmão é a causa principal de morte, representando aproximadamente 1.8 milhões de diagnósticos todos os anos a nível global. A forma mais agressiva de cancro do pulmão, o carcinoma de pequenas células, é expetável que represente 10 a 15% dos casos de cancro do pulmão.

O Nanolung, a solução proposta neste plano de negócios, é uma nanopartícula transportadora com três componentes funcionais, que permite distinguir as células saudáveis das células cancerígenas, parar a progressão tumoral e eliminar as células cancerígenas.

Tendências recentes sugerem que empresas bem estabelecidas são mais adequadas para atividades tais como ensaios clínicos e atividades de marketing, enquanto que empresas pequenas, como a Nanoplex, devem explorar áreas de nicho focadas em atividades cientificas. Habitualmente a junção destes dois tipos de empresas faz-se via fusões e aquisições, dadas as dificuldades financeiras das start-ups de base tecnológica em prosseguir para o mercado. Dito isto, a Nanoplex irá realizar um contrato de licenciamento da tecnologia após a segunda fase dos ensaios clínicos a uma empresa farmacêutica bem estabelecida.

A autora realizou uma análise de informação secundária tal como artigos científicos, livros académicos e websites de instituições relevantes para os temas em análise bem como recolheu e analisou informação primária através de entrevistas semi-estruturadas com profissionais com uma vasta experiência na indústria farmacêutica e particularmente na área de investigação e desenvolvimento de forma a validar o conteúdo deste trabalho.

Este plano de negócios permite afirmar que o Nanolung, um tratamento para o carcinoma de pequenas células, é viável em termos económicos e financeiros.

Palavras-chave: Inovação tecnológica, modelo de negócio, empresa startup e tratamento para o cancro do pulmão de pequenas células

Classificação JEL: M13, L65

Index

Figures index

Tables index

Abbreviations list

- CEO – Chief executive officer
- CIO – Chief of innovation officer
- FDA – Food and Drug Administration
- IND – Investigational new drug
- IP – Intellectual property
- NPV – Net present value
- NWC – Net working capital
- R&D – Research and development
- ROA – Return on assets
- ROE – Return on equity
- ROI - Return on investment
- SCLC – Small cell lung cancer
- VAT – Value added tax
- WACC – Weighted average cost of capital

Sumário executivo

A escolha deste tipo de tese de mestrado, plano de negócios, foi feita após a participação no programa COHiTEC, uma ação de formação em comercialização de tecnologias.

Este plano de negócios assenta numa tecnologia que visa tratar o cancro do pulmão de pequenas células, um problema que afeta aproximadamente 225 000 pessoas em todo o mundo. O cancro do pulmão de pequenas células tem a tendência de crescer e alastrar-se rapidamente, tornando o seu diagnóstico mais difícil, dado que em 2/3 dos casos as células cancerígenas já estão num estado avançado. A taxa de sobrevivência é de apenas dois a quatro meses caso não seja tratável e de seis a oito meses caso o doente faça quimioterapia. Esta doença reage à quimioterapia, no entanto, as recaídas frequentes fazem com que os doentes não consigam sobreviver. O progresso clinico desta doença tem sido lento, no entanto, estudos pré-clínicos recentes revelaram um número considerável de novas possibilidades por explorar.

O Nanolung, a solução proposta neste plano de negócios, é uma nanopartícula transportadora com três componentes funcionais: anticorpo, terapia genética e um fármaco anticancerígeno. Esta tecnologia permite distinguir as células saudáveis das células cancerígenas, parar a progressão tumoral e eliminar as células cancerígenas.

Após uma análise da indústria farmacêutica, é possível afirmar que aquela se aproxima do modelo económico de concorrência pura devido à elevada competição e à evidente grande procura neste mercado. Esta indústria está a enfrentar um crescimento especialmente acelerado dado o aumento de doentes com necessidades por satisfazer. Embora existam algumas barreiras como por exemplo um processo de investigação e desenvolvimento extenso e consequentemente com elevado investimento financeiro, esta indústria está mais aberta a colaborações com diferentes intervenientes assim como pequenas e médias empresas, em que a sua principal atividade é a investigação e desenvolvimento.

Tendências recentes sugerem que empresas bem estabelecidas são mais adequadas para actividades tais como ensaios clínicos e atividades de marketing, enquanto que empresas pequenas, como a Nanoplex, devem explorar áreas de nicho focadas em atividades cientificas. Habitualmente a junção destes dois tipos de empresas faz-se via fusões e aquisições, sendo esta uma estratégia desejável para a Nanoplex dadas as dificuldades financeiras em garantir uma posição sustentável e uma quota de mercado substancial nesta indústria tão competitiva.

Parcerias e aquisições de empresas startups, representam um quarto a um terço da gama de produtos das grandes farmacêuticas.

A estratégia definida teve em conta as características específicas do produto assim como a caracterização do tipo de competição existente. Neste sentido, a empresa adotará uma estratégia competitiva de diferenciação mas também de focalização. Embora a vantagem competitiva do produto seja a diferenciação perante os seus concorrentes, sendo o cancro do pulmão de pequenas células um segmento pequeno, optar por uma estratégia de focalização é igualmente adequado.

Quanto ao investimento, será necessário angariar 9 504 704,61€ para garantir o sucesso da empresa nas atividades de investigação e desenvolvimento. O estudo de viabilidade económica e financeira confirma que a Nanoplex irá gerar resultados financeiros suficientes para que seja considerado um bom investimento e, em consequência captar o interesse de investidores em todas as fases do processo. Esta conclusão verifica-se pelo valor atual líquido de 438 329 112,30€, uma taxa interna de rentabilidade de 261,46% e um *payback period* de cinco anos e quatro dias.

1. Introduction

This business plan aims to investigate the economic and financial viability of Nanoplex' SCLC treatment, Nanolung. Nanoplex will be a global prestigious research and development company and will license their innovative technology to a well-established pharmaceutical company.

Firstly, the author provides a description of the project along with the identification of the promoters of the project.

Secondly, a literature review will be conducted focused on the themes of technological innovation, business model, startup company, small cell lung cancer and analysis tools that will be used during the elaboration of the business plan.

In the methodology chapter the research question is presented, as well as the specific objectives and the author will explain which methods of research will be used.

Then, there will be a description of the new product that will be describe the opportunity and the technology.

Moreover, a market analysis will be conducted to understand the exterior environment where Nanoplex will be related. The author will perform this analysis by explaining how the pharmaceutical industry is characterized and its respective competition. Additionally, the author will execute a PEST analysis, five forces of Porter analysis and will identify the opportunities and threats.

Afterwards, it is important to analyze the internal environment of the company by presenting the internal structure of Nanoplex as well as identifying its strengths and weaknesses.

Then, in the competitive analysis the systemic SWOT is presented, combining the internal and the external analysis. Also the Ansoff matrix will be used to explain Nanoplex approach of the product extension.

The development strategy involves the vision, mission, values, objectives, SMART goals, critical success factors as well as resources, skills and strategic capabilities of Nanoplex.

After that, taking into consideration that the company will not commercialize the technology, it will be mentioned the implementation policies and requirements as well as respective financial forecasts.

1.1 Objectives of the business plan

The type of thesis that will be developed is a business plan, since the aim is to evaluate the economical and financial viability of an innovative technology to fight against small cell lung cancer.

This document will provide all the information to analyze the business opportunity and the strategy that will be set in order to successfully license the technology. In order to achieve that purpose, a clear description of the technology is the starting point to attract investors to finance the project.

In addition, a thorough analysis of market will be conducted to analyze the pharmaceutical industry and all the external factors intrinsic to this such as political, economic, social and technological. Moreover Porter 5 forces will be developed to have a better understanding of the industry as well as identification of opportunities, threats, strengths and weaknesses of the project.

Furthermore, a structured strategy will be defined taking into concern all the implementation policies and requirements such as product, price, communication, exit strategy, milestone map and risk planning.

Lastly an accurate financial evaluation will help to determine the feasibility of this product in terms of value creation.

1.2 Description of the project and identification of the promoters

The choice of this thesis was made after the author's participation in COHiTEC, a training program of technology commercial, from March to July 2015 with the partnership of INDEG-IUL. This program aims to assess the commercial viability of products or services that can be achieved from technologies of the participant researchers by having the support of management students and mentors, who contribute with their management skills.

Nanolung, was developed in the Cohitec sessions with the participant researchers Sergio Silva, Ph. D. of the Faculty of Pharmacy of University of Lisbon, and Raquel Teixeira, Ph. D. of the Faculty of Pharmacy of the University of Coimbra.

The mentors of the project were Nuno Serra, Manager at Unisys Portugal and Paulo Amaral, Quality director at Recipharm Lisbon. The mentors' contribution was essential to achieve the final results due to their management and pharmaceutical experience.

The technology was developed by Professor Mafalda Videira of the Faculty of Pharmacy, University of Lisbon with collaboration of her mentoring Master and Ph.D. students, one of them Sergio Silva.

Nanolung is a therapy against small cell lung cancer that is able to target and kill specific cancer cells.

Small cell lung cancer is a rare disease and the most aggressive form of lung cancer with an early tendency for dissemination. This rare disease is responsible for approximately 240 thousand deaths per year and has a 5-year survival rate lower than 5%.

2. Literature Review

2.1 Technological innovation

Innovation is driven by the ability of companies to see connections, to spot opportunities and to take advantage of them, because if they do not invest in innovation they put their future at risk. Porter (1990) refers that companies achieve competitive advantage through acts of innovation. Additionally refers that they approach innovation in its broadest sense, including both new technologies and new ways of doing things.

As stated by Oldham et al. (2004), innovation is the process or final product that develops from a novel idea, leading to a new creation. Incremental innovation refers to adaptations of an existing product or procedure and is low-risk, while radical innovation comes from revolutionary ideas and carries high risk (D'Innocenzo et al., 2012).

Christensen and Anthony (2012) define disruptive innovation as making the complicated simple, making the expensive affordable, driving growth by transforming what exists and creating what doesn't.

Innovation is often considered the most important characteristic associated with success. As stated by Tidd and Bessant (2013), innovation matters, not only at the level of the individual enterprise, but increasingly as the wellspring for national economic growth.

Davila et al. (2013: 1) refers that for any organization, innovation represents not only the opportunity to grow and survive but also the opportunity to significantly influence the direction of the industry.

Innovation is a network that includes inside (R&D, marketing) and outside (customers, suppliers). To innovate, this network needs to be maintained as an open and collaborative force.

Innovation can contribute to value creation in several ways. Academic research suggests a strong correlation between market performance and new products. New products are able to capture and retain market shares and increase profitability in those markets. Also, new product development is an important capability since the environment is constantly changing and shifts in the socio-economic area create opportunities and constraints. While new products are seen as an innovation in the marketplace, process innovation plays as well an important strategic role keeping the organization coping with the constant environmental changes.

Commercialization is known to be a critical stage of the technological innovation process, mainly because of the high risks and costs that it entails, (Chiesa and Frattini, 2011). This phase is consider critical due to difficulties that companies face in commercializing technological innovation such as volatility and proliferation of new technologies. Commercialization decisions like timing, target, distribution and price, have direct influence of the support from the innovation's adoption network and the post-purchase attitude of early adopters.

The most common misunderstanding is that innovation is primarily, if not exclusively, about changing technology. However, high-performing companies innovate by leveraging customer insight to develop new business models and improved technologies to create important value for the consumers and the company.

Davila et al. (2013), defined the six levers of innovation that affect how a company creates, sells, delivers and monetizes value to its customers.

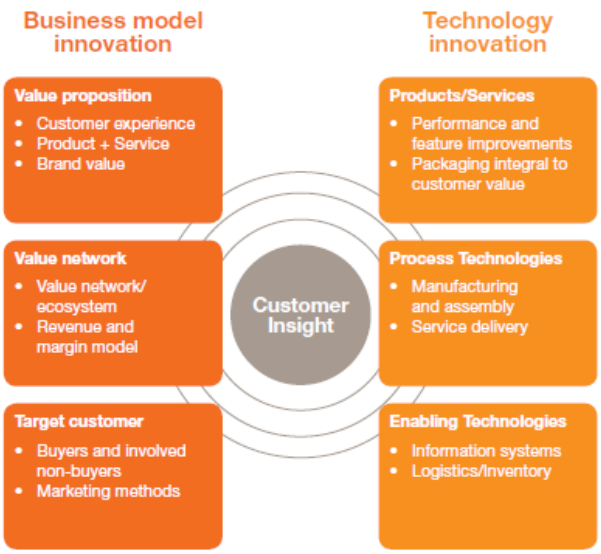

Figure 1 - Business model innovation and technology innovation

Source: Owning the disease: A new transformational business model for healthcare

On the business model innovation side, innovation is intended to create new value for customers by using products and/or services to deliver complete solutions, delivering and monetizing in new ways and find new or under-served customers. The later a crucial but often ignored form of innovation.

The three technology innovation levers provide new technologies that enhance existing products and/or services, by improving processes of manufacturing, delivering and providing support to the other levers.

If focusing only on the business model side or in the technology side, it will severely restrict the possible benefits and impact of the potential innovation. When both sides are combined, companies are able to create and deliver blockbuster innovations. The application of this framework in the pharmaceutical industry gives the opportunity to companies to rethink where they want to be in the future.

In order to own the disease, pharmaceutical companies, are not just changing the products that they offer but as well as reaching new patients by tackling unserved markets, meet unmet medical needs and do a better job of serving existing patients by managing patient outcomes. These new business models are more suitable for the future of healthcare, where radical innovation is a requirement together with more incremental innovations.

2.2 Business Model

As stated by Davila et al. (2013: 14), typically, when people think about innovation, they think of technological innovation. However, business model innovation is equally important and powerful in driving business success and in revolutionizing industries. Business models describe how the company creates, sells, and delivers value to customers, and it includes in the description the supply chain, targeted customer segments, and the customers' perception of the delivered value (Davila et al., 2013: 14).

Business model innovation for sustainability are innovations that create significant positive or significantly reduced negative impacts for the environment and/or society, through changes in the way the organization and its value-network create, deliver and capture value or change their value propositions (Bocken et al, 2014).

Pharmaceutical industry executives understand the new business environment, however, they are still resistant to change their current business models. The main reason is that the current business model is working, still allowing high margins and solid growth and the projections show that it will continue in the short and mid-term. Nevertheless many companies are being criticized by their shareholders, investor and regulators for their lack of innovation being the reflection of dry pipelines. According to Barei and Pen (2014), the lack of improvement in product pipeline shows that continuing to increase R&D expenses will not eliminate the shortfall in product output nor will increase process efficiencies or organizational restructuring.

As stated by Chesbrough (2010), the economic value of a technology remains latent until it is commercialized in some way via a business model. The same technology can be commercialized in different ways and the return will be different in those. For instance, a technology can be implemented in a business model already familiar to a company, while, on the other hand, the company have a business model that can make use of the technology via licensing. Moreover, there are still cases where a new technology does not have a specific business model and the managers must explore a new and more appropriate business model in order to capture value from that technology.

The ecosystem is expeditiously changing too fast for the pharmaceutical industry to respond, so companies need to create partnerships among each other. Recent trends suggest that big generic companies are more adequate to the operations regarding clinical trials and marketing drugs, while small companies should explore niche areas with a strong science-based focus.

2.3 Startup company

As stated by Bessant and Tidd (2011: 28), innovation needs an innovative organization in which the structure and climate enables people to deploy their creativity and share their knowledge to bring about change. Though, it needs to determine the appropriate organization given the operating facts. This is one area where start-ups often have a major advantage – by definition they are small organizations (often one-person ventures) with a high degree of communication and cohesion (Bessant and Tidd, 2011: 28).

Only "high growth potential entrepreneurs" are strictly beneficial in terms of contributing to economic growth and innovation; others (the "typical" entrepreneurs) may in fact be rather inefficient (Anokhin and Wincent, 2012). Additionally the authors state that individual entrepreneurs are considered to be the driving force of innovative development in economies; they either discover opportunities or create them and exploit these opportunities via start-up firms.

Christensen and Anthony (2012), highlighted the fact that disruptive innovations are typically introduced by startups, the rebel forces in the business universe.

Pharmaceutical industry includes thousands of small firms, start-up companies, usually thought of as a company in its first years of business, that works to solve a particular problem where the solution is not obvious and success is not granted.

Mergers or acquisitions are often used as exit strategies for these small firms, due to their financial difficulties to pursue to the market. Partnerships and acquisitions of pharmaceutical start-ups, represent one-quarter to one-third of most large companies' pipelines.

In order to forecast revenues, it is needed to consider market size, market share and market growth of the start-up potential drug or drugs. To determine the market size, it is necessary to consider the number of patients receiving the treatment, the price of the treatment per patient and existing sales data to similar products.

Startup face a highly regulated industry, with increasing research & development costs, escalating costs of litigation, growing threats to patient life and a constant entry of new competitors. Research did by DiMasi, et al. (2013) shows that only 32% biologics that entered phase I trials were approved. On the same study, the authors provided evidence that the approval rate was even lower for the oncology biologics, only 12%. In 2012, only 15,4% of

all orphan drugs (treatments for diseases affecting 200.000 or fewer people) in the US were approved.

Small companies also often license-out their novelty drugs to more experience firms for further development phases, regulatory review and commercialization.

2.4 Small cell lung cancer

According to the American Cancer society, Lung cancer (both small cell and non-small cell) is the second most common cancer and is by far the leading cause of cancer death in both men and women. Lung cancer accounts for approximately 13% of all new cancers diagnosed every year worldwide (1.8 million cases) being responsible for approximately 1.6 million deaths in 2012 with a growth rate of 13.5%.

There are two major types of lung cancer: small cell lung cancer (SCLC) and non-small cell lung cancer. Small cell lung cancer, the most aggressive form of lung cancer, accounts for about 10% to 15% of all lung cancers. This rare disease tends to grow and spread quickly, and the majority of cases spread to distant parts of the body before it is found. This type of cancer is responsible for approximately 30 thousand patients annually and the 5-year survival rate is a dismal 6%.

In around two-thirds of the cases the cancer cells are already in a later stage due to the difficult detection of the disease. The median survival rate is only 2 to 4 months if untreated, and survival increases to 6 to 8 months with chemotherapy. This disease is responsive to chemotherapy, but frequently relapses, and patients succumb to the disease in a few months.

It is clear that the treatment of SCLC remains a significant challenge for oncologist and new therapeutic approaches are urgently needed to improve patient outcomes of this disease as well as to improve patient quality of life. As stated by Abidin et al. (2010), there has been an increase on the effort to understand the molecular biology of SCLC and to exploit this knowledge for therapeutic control through the development of so-called targeted therapies. According to Carillio et al. (2014), a large number of molecular-targeted drugs and immune-modulators are currently in clinical development: however, only a better understanding of molecular markers predictive of response to targeted agents will lead to real advances in the treatment of SCLC.

Limited SCLC tumor tissue availability for diagnosis and study contributed to a decreased research attention to this disease. In the 2012 fiscal year, the National Cancer Institute

research portfolio contained 745 projects that included lung cancer research, but only 17 (approximately 2%) of those studies has a focus on SCLC (Pietanza et. al, 2015).

Clinically meaningful progress has been slow in SCLC, although recent preclinical and clinical correlative analyses have pointed to a number of new targets of interest (Pietanza et. al, 2015).

2.5 Analysis tools

2.5.1 Pest analysis

In 1967, Francis Aguilar developed a tool for scanning the business environment called ETPS (economical, technical, political and social), as the four environments that must be scanned when looking for analytical grounds to support the strategic plans. Afterwards, in the 1960s, Arnold Brown emphasized the same environmental factors but labeled them differently, STEP (social, technical, economic and political). Then, this macro external environmental analysis was modified to STEEP (social, technical, economic, environmental and political).

In 1980, several authors such as Porter, Fahey, Narayanan, Morrison, Renfro, Boucher and Mecca included a variety of orders like: PEST (political, economic, social and technological) and PESTLE (political, economic, sociological, technological, legal and environmental).

According to Gupta (2013), the underlying thinking of the PEST analysis is that the enterprise reacts to changes in its external environment. Additionally, Gupta (2013) states that this reflects the idea that strategy requires a fit between internal capabilities and the external environment.

2.5.2 Porter Five Forces

Porter' Five Forces model was developed by Michael E. Porter in the late 1970s. The five forces model is a simple but influential tool for the identification where power lies in a certain business situation by using the outside-in perspective (Johnson et. al, 2008).

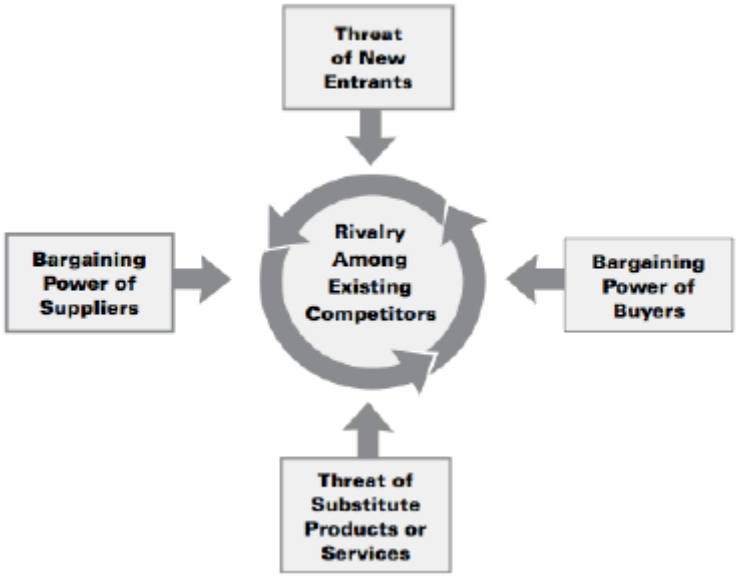

Figure 2 - Five forces of Porter

Source: The five competitive forces that shape strategy

In order to develop a strategy, it is crucial to have a deep knowledge about the industry in which the company operates taking into concern all the factors that can influence the company within an industry. Besides rivalry among the existing competitors, Porter's Five Forces model identifies another four forces that characterize the dynamics within an industry: bargaining power of Supplier, bargaining power of buyer, threat of substitutes and threat of new entrants (Porter, 1979). Porter's essential message is that if these five forces are high, then industries are not attractive to compete in (Johnson, 2008: 60).

The force rivalry among existing competitors includes several forms of competition, such as "price discounting, new product introductions, advertising campaigns, and service improvements" (Porter, 2008: 32).

The threat of entry depends on the extent and height of barriers to entry (Johnson, 2008: 61). These typical barriers are scale and experience, access to supply or distribution channels, expected retaliation, legislation or government action and differentiation.

The force threat of substitutes consists on products or services that offer similar benefit to an industry but by a different process.

Regarding the power of buyers, this can be concentrated buyers: where a few large customers represent for the majority of sales, then buyer power is increased; low switching cost: where buyers can easily change between one supplier to another due to the strong negotiating

position since suppliers are desperate for their business; and buyer competition threat: if the buyer has some facilities to supply itself or has the possibility to acquire those facilities.

The power of suppliers tends to be high where they are concentrated suppliers, a few producers dominate the supply; high switching cost, if it is too expensive for buyers to change constantly the suppliers, then buyers become quite dependent; and supplier competition threat, when suppliers are able to cut out buyers that are acting as intermediaries.

2.5.3 SWOT analysis

The traditional planning school in strategic management is driven by a conception of balance as a strategic balance between existing internal resources and external opportunities (Bordum, 2010). Ansoff, Steiner, Andrews and Humphrey developed the basic elements of the planning school (Ansoff, 1965; Steiner, 1969; Andrews, 1971).

They were all affected by the work in the Stanford Research Institute's (SRI) Strategic Intelligence Program, where the term stakeholder was coined in 1963 to define those who had a critical interest in the operation and success of an enterprise and where the strengths, weaknesses, opportunities, and threats (SWOT) analysis was also developed (SRI Timeline of innovations).

The original analysis name was SOFT standing for satisfactory, opportunity, fault and threat. We started as the first step by asking "What's good and bad about the operation?" Then we asked, "What is good and bad about the present and the future?" What is good in the present is satisfactory, good in the future is an opportunity; bad in the present is a fault, and bad in the future is a threat (Humphrey, 2005).

The SOFT analysis was organized with time being operative through a distinction between present state and future state, and not organized as in the SWOT analysis, being operative in space through a systems theoretical distinction between internal system and external environment (Bordum, 2010).

The SOFT analysis evolves into SWOT analysis with a focus on objectives and the strategic balance of a firm to its environment. The SWOT analysis freezes the distinction between internal resources (S-W balance) and external opportunity (O-T balance) (Bordum, 2010). SWOT summarises the key issues from the business environment and the strategic capability of an organization that are most likely to impact on strategy development (Johnson, 2008).

2.6 Frame of reference

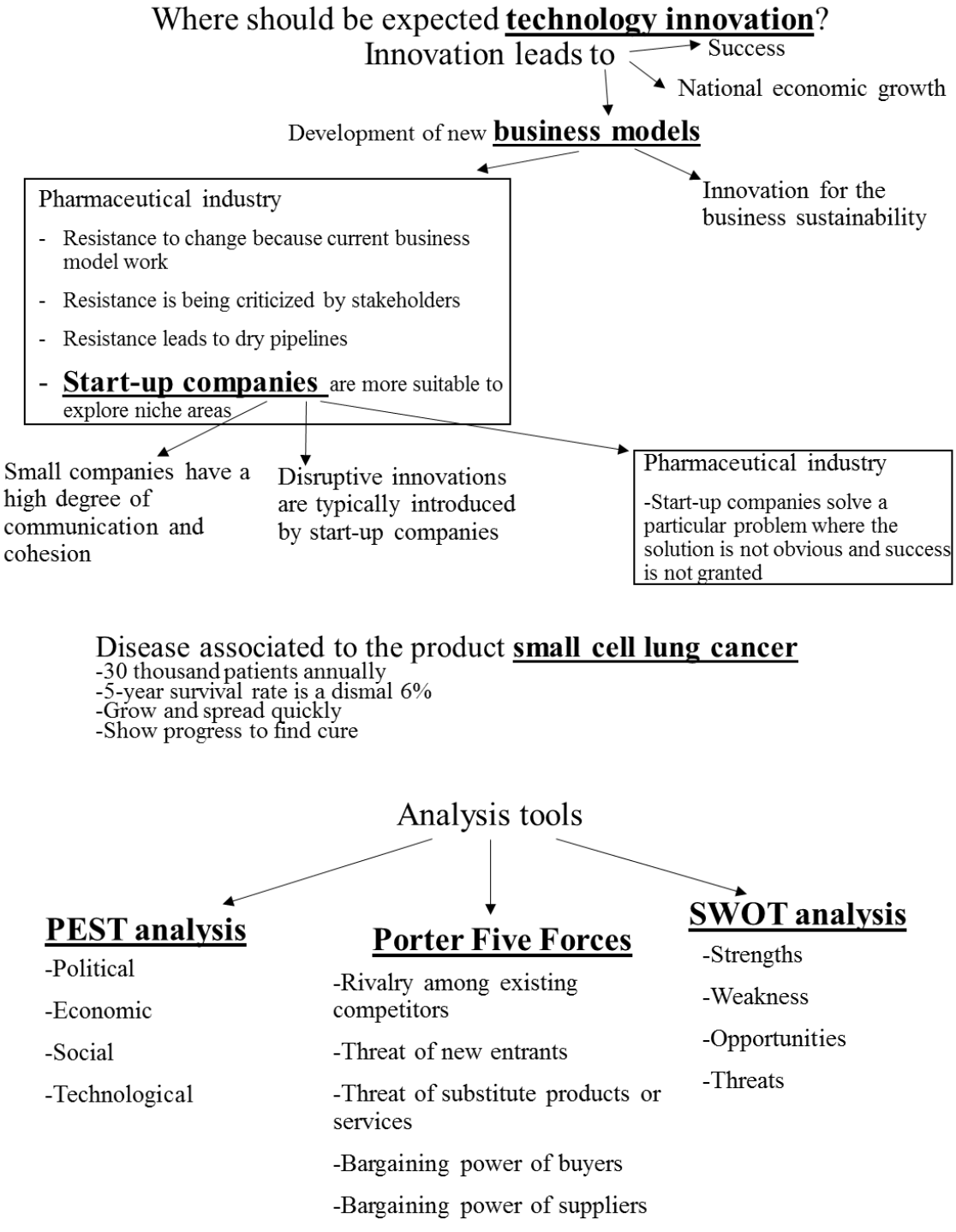

Figure 3 - Frame of reference

Source: Author on the basis of the literature review

3. Methodology

3.1 Research question

A clear definition of the research question, will give focus to the author when developing the business plan by providing guidance and consistency. Additionally, it delimitates the study and guides the literature review to the central issue.

The research question of this project is:

Is Nanolung, a treatment against Small Cell Lung Cancer, economically and financially viable?

The author considers that the question is relevant for the reason that is a novelty treatment for small cell lung cancer, a rare disease that currently has no cure, and preliminary studies indicate that the therapy will be a success.

On the other hand, the research question suits the criterion clear, in the way that the reader understands what is the purpose of this project. When questioning if a product is economically and financially viable, it implies a financial evaluation and all the preliminary and complementary business opportunity analysis.

Since this treatment is only addressing the Small cell cancer patients instead of the bigger lung cancer market, it is also considered a suitable research question regarding feasibility.

3.2 Objectives

Since this project will be developed as a business plan, objectives must be set to support the answer to the proposed research question:

Is Nanolung, a treatment against Small Cell Lung Cancer, economically and financially viable?

Once the research question is defined, specific objectives need to be mentioned. These objectives are a reflection on the central issue and intent to verify if the product is economically and financially viable.

As mentioned in the literature review, small research and development companies in the pharmaceutical industry usually focus in niche markets and most of the products are licensed to big pharmaceutical players. Having said that, the exit strategy of this project will be to

license the product Nanolung and the following questions were defined taking that into consideration.

1. Which countries will be willing to adopt this treatment?

2. What are the benefits that patients need to be satisfied?

3. What are the advantages this product has, since it is a treatment for an orphan disease?

4. What are the competitors of this treatment?

5. What differentiates Nanolung from the competition?

6. Which business model is more suitable for this product?

7. How should Nanolung be promoted to future investors?

The first and second question focus on the target of this product by questioning which countries are more willing to adopt this treatment through the analysis of previous similar treatments being adopted. Moreover, the understanding of benefits that patients need to be satisfied will be helpful since these need to be emphasized when the product is being promoted.

Third question emphasizes the fact that Nanolung is a treatment against an orphan disease and due to that this product has some advantages regarding time, cost and regulatory issues during the research and development process.

The next two questions (fourth and fifth) will allow a better understanding the competition and highlight what differentiates Nanolung from the other current solutions.

The sixth question involves defining what business model is more suitable for the type of company that Nanoplex is by analyzing what similar companies are doing in the pharmaceutical industry.

Lastly, the final question is regarding the communication strategy the company will adopt focusing on the future investors of the company, to whom Nanolung is going to be licensed.

3.3 Methodology

Methodology is a set of principles and rules that are implicit to the structure of thought. Research methodology is a process of selection of the strategy that better suits the objectives

defined for this business plan. Likewise, the techniques for gathering data should be appropriate to the same objectives.

Therefore, the author will follow an interpretative paradigm, by analyzing and understanding the reality of the product in study and setting the business development strategy for a successful implementation of the project.

Regarding data analysis, it will be used both qualitative and quantitative analysis. Estimating the costs and revenues on the economic and financial evaluation is an example of quantitative analysis, although a thorough study should be done to understand the economic and financial feasibility of project. Other example that would imply the use of quantitative analysis is the external and internal analysis.

3.4 Methods

The methods used to elaborate the project are based on the analysis of secondary data, scientific articles published on databases such as B-on and ABI/INFORM; academic books related to the issues addressed as well as websites of relevant institutions for the subject under analysis.

Additionally, the author collected and analyzed primary data through semi-structured interviews with two professionals with a vast experience in the pharmaceutical industry, particularly in the R&D areas. The semi-structured interview (often called a ‘conversation with a purpose’) allows the author to provide some structure based on her research interests and guiding the interview as well as allowing the interviewees enough space to follow different paths enriching the information collection process.. The questions (see attachment I) often serve as helpful guides for the participants. However, due to the vast experience of the professionals being interviewed, the semi-structured interview allows flexibility so that the author can obtain more pivotal information than the initially asked. The interviews were conducted to Dr. Ana Gonçalves, consultant for the pharmaceutical industry specialized in FDA inspections (see attachment II); and António Dinis, director of marketing and communications at Hovione (see attachment III).

4. Description of the new product

4.1 Opportunity

Cancer is a broad group of diseases in which cells divide and grow in an uncontrolled fashion, forming malignancies that can invade other parts of the body. In normal tissues, the rates of new cell growth and cell death are tightly regulated and kept in balance. In cancerous tissues, this balance is disrupted as a result of mutations, causing unregulated cell growth that leads to tumor formation and growth. While tumors can grow slowly or rapidly, the dividing cells will nevertheless accumulate and the normal organization of the tissue will become disrupted. Cancers can subsequently spread throughout the body by processes known as invasion and metastasis. Once cancer spreads to sites beyond the primary tumor, it is generally incurable. Cancer can arise in virtually any part of the body, with the most common types arising in the prostate gland, breast, lung, colon and skin. Dysregulated cell growth in vital organs such as the liver, lung or brain can impair their normal function with consequences that may ultimately lead to death.

Lung cancer is the leading cause of cancer death among both men and women. Lung cancer accounts for approximately 13% of all new cancers diagnosed every year worldwide (1.8 million cases) being responsible for approximately 1.6 million deaths in 2012 with a growth rate of 13.5%.

According to the American Cancer Society, SCLC, the most aggressive form of lung cancer, is expected to have around 10% to 15% of the 221,200 newly diagnosed lung cancer cases and the 158,040 deaths estimated to occur in the United States in 2015.

SCLC tends to grow and spread quickly, due to the difficult detection of the disease, 2/3 of the cases the cancer cells are already in a later stage. The median survival rate is only two to four months if untreated, and survival increases to six to eight months with chemotherapy. This disease is responsive to chemotherapy, but frequently relapses, and patients succumb to the disease in a few months.

Research by Corral et al. (2015), has provided information regarding costs for SCLC patients. The mean cost per patient was 15 418€ for limited disease and 12 482€ for extensive disease. Lower costs when the disease is presented in an advance stage is a reflection of the shorter

survival and lower tolerance to aggressive treatment as well as the limited treatment options available to patients. Chemotherapy was the major contributor to these costs (36.1%).

The need to demonstrate cost-effectiveness and estimate the budget impact of new interventions and therapeutic innovations requires consideration of the costs of treating the disease, including all therapeutic strategies, namely surgery, chemotherapy and radiotherapy (Corral et al., 2015).

As Dr. Duro da Costa, Director of Pneumology Dept. at IPO Lisbon, mentioned, “no significant progress has been done (regarding SCLC) in the past 20 years”. Clinically meaningful progress has been slow in SCLC, however recent preclinical and clinical correlative analyses have pointed to a number of new targets of interest (Pietanza et. al, 2015).

4.2 Description of the technology

Nanolung is a treatment against SCLC that is able to target and kill specifically SCLC cells.

The technology was engineered to be able to deliver the therapeutic agents directly to site where it is needed the most, the lungs. Inhalation localized therapy is a minimal invasive approach since it goes directly to the lungs. This approach avoids most severe side effects of chemotherapeutic drugs since the drugs will not be spread out throughout the body and will not affect other organs or tissues such as the hair follicles.

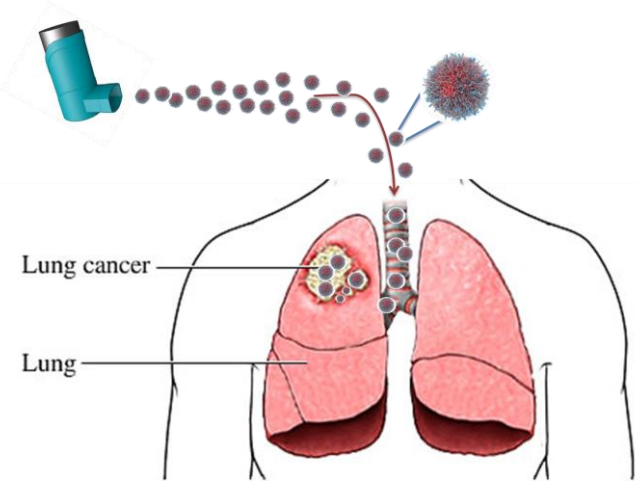

Figure 4 - Inhalation localized delivery

Source: Author

Nanolung technology is a nanocarrier with three key functional components: antibody, gene therapy agent and anticancer drug. When reached the lung, the triple functional inhalable

nanocarrier will be able to distinguish between healthy and cancer cells due to the antibody that is specifically designed to bind to receptors found only in SCLC cells. After the connection is made, the gene therapy agent will stand and will be able to stop tumor progression and reverse the cancer stage of the cells. These cells when detected are already in advance stage so by reversing the stage, these can be transformed to a point that it can be cured. Lastly, the anti-cancer drug is released into the cancer cells and kills them.

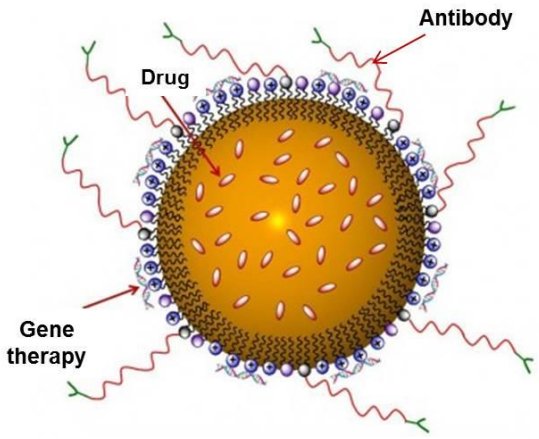

Figure 5 - Triple functional nanocarrier

Source: Author

With pulmonary administration and the triple functional nanocarrier, it is possible to increase the amount of drug without affecting the rest of the body. This novelty treatment will be able to overcome current unmet medical needs, reflecting in not only saving lives but also enhancing patients' quality of life.

All the intellectual property generated by Nanoplex solutions will be considered as a private property after being patented, providing therefore competitive advantages, which will grant Nanoplex, the right to exclude others from producing, using, or selling its invention.

In most countries, patents give a 20-year period protection from the date the patent is issued. However, the effective patent term is frequently less than 20 years because patents are often obtained before products enter the market. Considering the development stage of Nanolung, it is expected to reach the market in 2024, IP will not represent an obstacle for the success of Nanolung.

Since the technology is unique and has potential applications in the most desirable markets, the intention is to submit a patent of the technology as soon as possible in the main markets, namely USA, Europe and China.

5. Market analysis

5.1 Industry analysis

5.1.1 Industry map

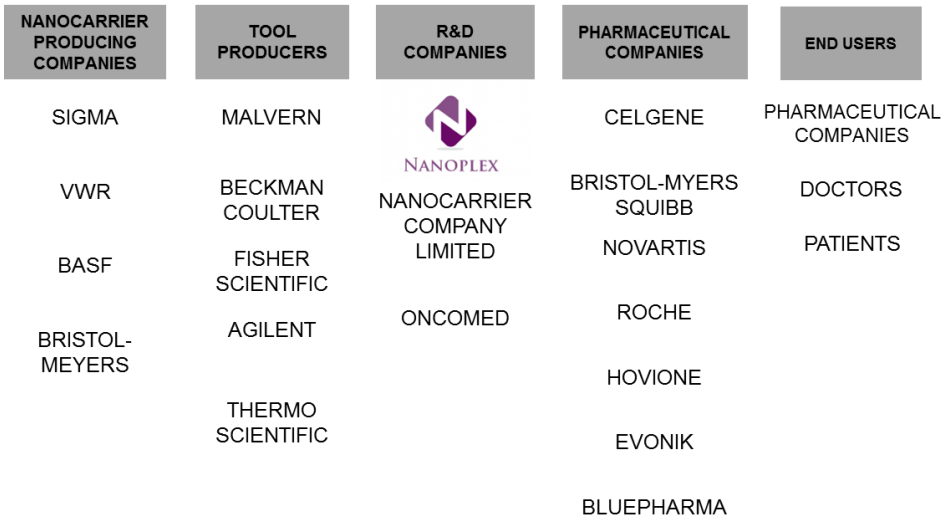

Figure 6 - Industry map

Source: Author

The global lung cancer therapeutics market has been driven by the adoption of personalized treatments. Novelty treatments have revitalized the lung cancer therapeutics market and on the other hand, patent expiry of existing drugs has posed a major threat to original drug producers. For that reason, manufacturers were pressured to cut down investments in research and development. In order for these companies to maintain its competitiveness and diversified portfolio, pharmaceutical companies are acquiring smaller research and development companies, like Nanoplex, or their products.

5.1.2 Industry characterization and competition

The pharmaceutical industry is characterized by its significant competition from many pharmaceutical and biotechnology companies that are also researching and selling products.

The main players in this industry are the large pharmaceutical companies and these have extensive financial, manufacturing, marketing, research and drug development resources. Also, these companies have large expertise in preclinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies and other public and private organizations are conducting research that may seek patent protection

with respect to potentially competitive technologies. These organizations may also establish exclusive collaborations or licensing their technologies with the main players of the industry.

Due to the significant competition and large market demand, the pharmaceutical industry is characterized by almost perfect competition.

This industry is facing a growing life cycle mainly due to the growth of patients with unmet needs to be satisfied. Although there are some barriers like extensive research and development processes, this industry is more open to collaborations with different players like small and medium enterprises which core business are research and development.

As it can be observed in BCG matrix below, Nanoplex is a question mark due to the high growth rate of the industry and the low market share when compared to the other players in this industry.

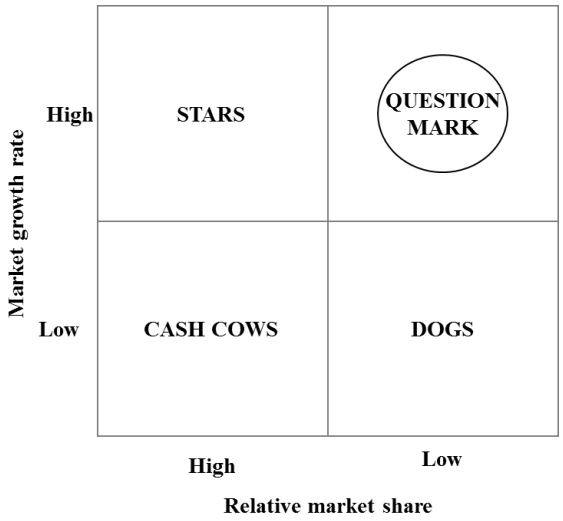

Figure 7 - BCG matrix

Source: Adapted from Introdução à gestão de organizações

GE/ Mckinsey matrix allows understanding the industry attractiveness as well as the Nanoplex competitive position in the pharmaceutical industry.

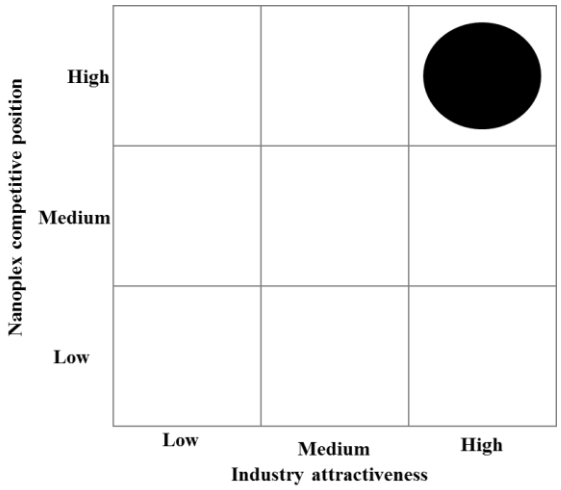

Figure 8 - GE/Mckinsey matrix

Source: Adapted from Introdução à gestão de organizações

Nanoplex competitive position is high giving the unique technology that will fulfill specific unmet needs and the qualification of their human resources giving the amount of years of experience on research. The high industry attractiveness is due to the enormous dimension of the market and increasing growth rate. As observed above, the circle reflects the major importance that this product represents to the company. Giving the position of the circle in the GE/Mckinsey matrix, this model recommends the investment for this one to grow.

For the purpose of this work it was considered as direct competitors the emergent therapies such as Cell therapies and Monoclonal Antibodies and also the conventional therapies such as chemotherapy.

Although Cell therapy is a direct competitor, they face a major disadvantage due to the longer time needed to be applied resulting a slower therapeutic process. Time is crucial in a fast evolution disease such as SCLC.

Also despite the fact that Monoclonal Antibodies are consider direct competitors, they can only identify the cancer cells and leave the immune system to attack them naturally. With Nanolung the cancer cells are identify and a proved effective anti-cancer drug eliminates them.

The major disadvantages of chemotherapy are related with I.V. administration, drug unspecificity and inability to discriminate between cancer cells and normal cells undergoing rapid division which will result in massive side effects. Since Nanolung is pulmonary

administrated and for that reason more focus on the source of the cancer, reduction of side effects is a benefit not achieve by our competitors.

Indirect competitors are the conventional therapies such as surgery and radiotherapy. These treatments are considered indirect competitors since they only produce positive results when combined with chemotherapy.

Analyzing the competition, Nanolung against advanced lung cancer, has a clear advantage since it can perform more effectively by being non-evasive which will reduce side effects and just for that patients and their families with be attracted to use Nanolung.

5.2 Pest analysis

Analyzing the **political/legal context**, pharmaceutical industry has faced an increased pressure on price however, in the oncology area, cost of treatments continue to rise around the world since it offers innovative treatments for diseases with few other options. The increase cost of treatment not only affects patients and their families, it affects the society. Politicians offer new plans to increase votes and health institutions encourage doctors to asks patients for their money. The high cost of treatments can also be associated to the many legal existing restraints to releasing drugs suitable for human consumption. Before the treatment is allowed to be studied in humans, FDA requires extremely thorough preclinical tests such as *in vitro* (studies conducted in the laboratory) and *in vivo* (studies in living cell, tissue cultures and animal models) tests. These nonclinical studies, contribute to a better understanding of the treatment mechanism of action as well as provide evidences that the treatment is reasonably safe to conduct the proposed clinical trials. Afterwards, starts the recruitment and enroll of volunteers to participate in clinical trials and this phase can take months since there are often specific requirements for enrollment, based on the nature of the condition studied and the patient group that is expected to benefit from the novelty treatment.

Regarding the **economical context**, global economic crisis still exists, however, OECD Health Statistics report show that the spending on healthcare per capita continues to grow. Increased pressures from shareholders caused a consolidation of the industry and more mergers and acquisitions will continue to take place in the coming years. Also venture capitalists are more willing to offer funding for new industry players like biotechnology companies.

Concerning the **social aspect**, patients are becoming more and more informed about the innovations available and consequently become more demanding. The continuous innovation has increased patient's expectation to acquire the best available services and products. Also emerging markets have shown enormous populations with high levels of unmet needs creating a gap in the market ready to fulfill. In addition, the continuous research and development process requires more qualified human capital.

Due to fast **technology** evolution in the industry, companies need to update frequently to avoid being left behind. These need to be the first to implement novelty technologies to gain the first mover advantages in this competitive market.

5.3 Five forces of Porter

Threat of new entrants (Low)

The pharmaceutical industry has high entry barriers mainly since companies need to allocate a lot of capital into research and development, patent expenses, distribution and marketing expenses before having the return on the capital.

On the other side, big pharmaceuticals are able to build global operations and benefit from economies of scale in terms of manufacturing and distribution. A new entrant lacks the strong brand name as well as reputation and necessary network able to facilitate this process and reduce cost.

Patent expirations lead to an entry of new competitors (generic competition) causing decreased revenues. The ability for a pharmaceutical company to offset the loss of revenue from patents' expiration, depends on the growth of existing products and also the growth of novelty products or services to be introduced in the company pipeline.

Rivalry among existing competition (High)

The pharmaceutical industry is characterized by being a mature, consolidating and highly competitive industry. Companies have strong credit profiles with high margins, healthy balance sheets and good liquidity.

For small and medium enterprises to stay alive in this industry they need either a potential "blockbuster" in their pipeline or significant research or valuable assets that will be licensed to big and strong pharmaceutical company.

Intellectual property protection tends to reduce competition between pharmaceutical industries. Although, companies can always try to submit a patent with a similar technology for treating the same health condition however using a different approach. Consequently this will increase rivalry between the companies.

Bargaining power of suppliers (Low)

Large number of suppliers and the importance that each pharmaceutical company represents to them are the main reasons why usually suppliers have no negotiation power. The resources required to produce products or services are not restricted to a limited set of suppliers.

Bargaining power of buyers (Low)

Generally consumers have no power of negotiation. They consume medication that is prescribed by the doctors, the only option is generic but in the oncology area this is not a common practice. Patients will acquire the product or service that will better fulfill their unmet needs.

Threats of substitute products or services (Medium)

Generic competition can be a threat for the pharmaceutical industry and even for some cases in oncology area. However generally and for the specific case of small cell lung cancer, the choice will be the most efficacy proved products and novelties that proved fulfill unmet needs.

Normally, when a new product is introduced in the market, no better alternatives are available. It takes a long amount of time to place a product in the market, during this period, the first mover will gain recognition and reputation. Also, patent protection will allow keeping in secret all the technology information and prevent others from producing the same product. However, when patent protection period finishes, the information is disclosed and the threat of substitute products or services increases.

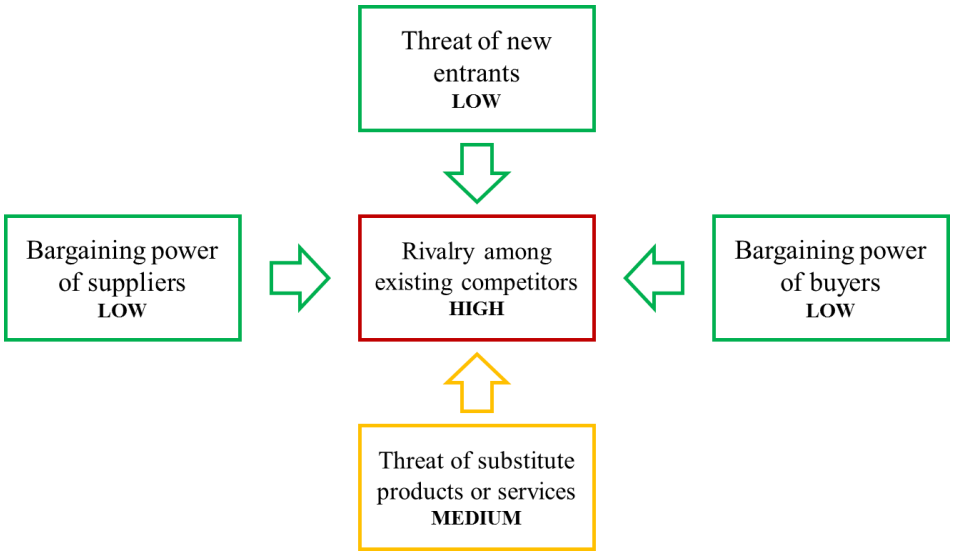

Figure 9 - Five forces of Porter of the pharmaceutical industry

Source: Author

In a nutshell, the pharmaceutical industry has high entry barriers given the amount of financial resource necessary and for that reason the threat of new entrants is low. Both bargaining power of suppliers and buyers have low forces as it can be observed in figure 11. The second highest score belongs to the threat of substitute products or services, due to the patent protection of products and also due to the amount of time and resources needed to place a product or service in the market. Lastly, this industry is characterized by being a mature, consolidating and highly competitive one. For that reason the highest force is rivalry among existing competitors. Given this scenario, it can be consider a relative high attractive industry with an average of 2.86 global evaluation.

	Industry attractiveness					Industry attractiveness				
	Very low	Low	Medium	High	Very high	Very low	Low	Medium	High	Very high
Competitive forces	**Present**					**Future**				
Threat of new entrants	2,85					2,86				
Rivalry among existing competition	4,3					4,5				
Bargaining power of suppliers	2,4					2,4				
Bargaining power of buyers	2,81					2,81				
Threats of substitute products or services	3,5					3,5				
Global evaluation	**2,85**					**2,86**				

Table 1 - Quantitative five forces of Porter of the pharmaceutical industry

Source: Author

5.4 Identification of opportunities and threats

Opportunities

As mentioned on literature review, Pharmaceutical companies are experiencing an evolution on their business models. Big pharmaceutical companies are opting to acquire, or do mergers with small and medium enterprises that focus on research and development such as Nanoplex, instead of investing on their own research and development departments.

The ability to establish strategic agreement with pharmaceutical companies will boost Nanoplex research and will place its name in the market. Though acquisitions and mergers are opportunities for small and medium enterprises to gain reputation and increase their credibility to future investors as well as patients. In addition, these partnerships allow a global penetration and market leadership through distribution channels and marketing activities.

Nowadays, is occurring an increased awareness about healthcare needs and cancer has been one of the most discussed topics. An increased awareness leads to an increased demand for more healthcare solutions, especially healthcare solutions that can not only treat the problem but as well ensure patient's life quality during the treatment period.

Threats

This industry is characterized by its fast technology evolution, thereby reaching the market as fast as possible is crucial for successful new product.

Although novelty products with patent protection cannot be imitated, competitors can always try to submit a patent with similar technology to treat the same disease however using a different approach.

Investments on start-up pharmaceutical companies are crucial especially during the research and development phase. If no companies show interest and invest, start-up companies cannot survive in this industry. Also these investments can be negatively affected by the global economic slowdown resulting on the lower probability to receive them.

6. Internal analysis

Once the external factors are analyzed, matters to characterize the internal context of Nanoplex, starting to describe the organizational structure and afterwards identify the strengths and weaknesses of the company that will allow to keep competitive advantages in this competitive industry.

6.1 Organizational structure

As it can be observed in the figure 10, Nanoplex will have a simple structure, focusing on the research and development process and promotion of the technology to future investors.

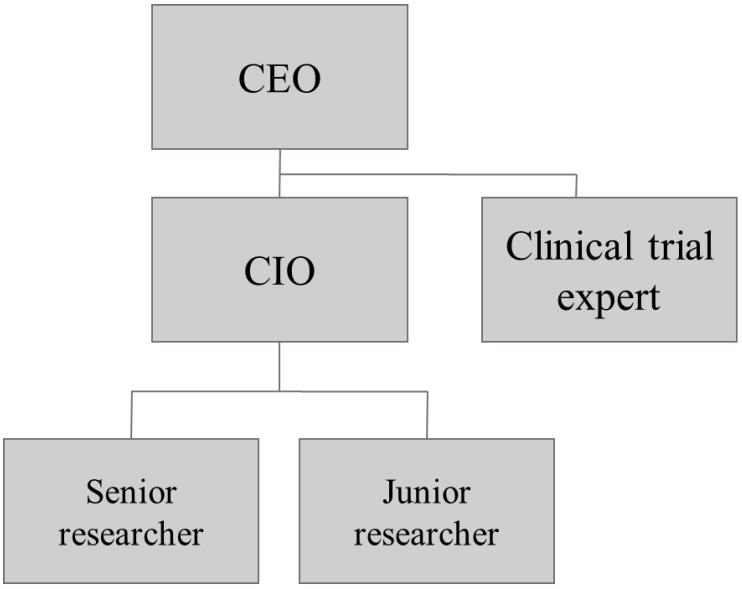

Figure 10 - Nanoplex organizational structure

Source: Author

Nanoplex will count with a CEO (Chief executive officer) on the top of hierarchical structure, who will set the company' strategy and direction; following by the CIO (Chief of innovation officer) that will have the responsibility to coordinate all the research and development activities and will be in charge of two researchers, one with more experience in the field. Moreover, a clinical trial expert will be recruited in 2019, the first year of clinical trials, in order to give guidance and ensure that all the procedures are in accordance to standard and guarantee the Nanolung' success in clinical trials.

Chief Executive Officer

Especially in a start-up company, the CEO is responsible for the success or failure of the company. The CEO will be the responsible for all the management activities and will have the Chief of Innovation Officer reporting directly to him.

The CEO will be responsible to set and implement the strategy that is the most suitable for Nanoplex. In addition, he/she will have the responsibilities to manage the firm capital, target and initiate strategic business partnerships, identify risks and ensure appropriate strategies are

in place, recruit human capital and deal with day-to-day decisions. The CEO will be also in charge of promoting the project, namely to ensure the adequate flow of funds.

Chief of Innovation Officer

The Chief of Innovation Officer is the bridge between the scientific and the business part of the company. Works with as well as reports to the CEO to develop and manage new ideas and their implementation throughout the organization, specifically addressing R&D issues.

This professional will be responsible for all the research and development activities from the planning to the implementation. Moreover, it will coordinate the work of the two researchers.

6.2 Identification of strengths and weaknesses

Strengths

Nanolung is a treatment against SCLC and since it is a rare disease, this treatment is considered an orphan drug. As stated by Richter (2015), despite variation in the terminology and prevalence thresholds used to define rare diseases among different jurisdictions and organizations, the terms “rare disease” and “orphan drug” are used most widely and the average prevalence threshold is between 40 and 50 cases/100,000 people. This designation allows Nanoplex to receive orphan tax credits, which can provide incentives to develop some drugs for a class of indicators. In addition, Nanoplex may also have lower clinical development costs, as clinical trials sizes are lower given that less patients are required. This FDA program, begun in the early 1990s, allows to speed new treatments for serious or life-threatening diseases for which there are no adequate treatment.

Due to the minimal invasive approach of Nanolung, most severe side effects of chemotherapeutic drugs will be avoided since the drugs will not be spread out throughout the body and will not affect other organs or tissues such as the hair follicles.

Nanoplex technology is patentable which prevents any competitors from commercially making, using selling, importing or distributing this technology. In addition, this technology has the potential to be used in various applications such as pulmonary diseases diagnose kit and pharmaceutical nanocarrier development services.

Nanoplex has strong scientific background due to the fact that Nanoplex human capital is a research group that has been doing research in the cancer field for more than 15 years.

Weaknesses

If a proposal to be acquired by a pharmaceutical established company does not happen, the company financial and human resources will not be enough to survive in this competitive market especially given the costly and lengthy research and development process of Nanolung.

Additionally, being a star-up company with lack of capital funds, increases the dependency on investments in order to achieve their milestones and keep their human capital employed.

Although Nanoplex has strong scientific background, it lacks in business experience.

7. Competitive analysis

7.1 Systemic SWOT

	Strengths	Weaknesses
	- Orphan drug tax credits and lower research and development costs - Technology base supports a range of applications (pulmonary diseases diagnose kit and pharmaceutical nanocarrier development services) - Patentable technology - Nanoplex has a strong scientific background	- Costly and lengthy research and develop process -Dependency on investments and proposal from a pharmaceutical company to license Nanolung, in order to be alive in this competitive market - Lack of business experience -Start-up companies dependency on investments
Opportunities	**Challenges**	**Constraints**
- Evolution on pharmaceutical business models - Acquisitions and mergers with big pharmaceutical companies - Increased awareness about healthcare needs leads to an increased demand for more healthcare solutions	- Development of a wide range of products or services - Communication with investors and well establish pharmaceutical companies	- Costly and lengthy research and development phase - Nanolung can only reach the market if Nanoplex license the technology
Threats	**Alerts**	**Danger**
- Fast technology evolution - Competitors can try to submit a patent with similar technology - Investments are crucial for start-up companies to survive in a competitive industry -Economic slowdown can affect negatively investments	- Development of additional products/services to Nanoplex' pipeline - Define strategies aligned with risk planning	- Not able to attract investments to proceed with all stages of the research and development process - Not able to license Nanolung - Disclosure of technological information regarding Nanolung

Figure 11 - Systemic SWOT analysis

Source: Author

7.2 Ansoff Matrix

Igor Ansoff created Ansoff Matrix and it was firstly publish in his article "Strategies for Diversification" in the Harvard Business Review in 1957. This tool is crucial for Nanoplex integration in the industry, since it shows the different approaches that allow the company' growth.

Given Nanoplex is launching its first product, in an existing market but it is not been explored by the company and since market needs already exist, Nanoplex approach is product extension (figure 12).

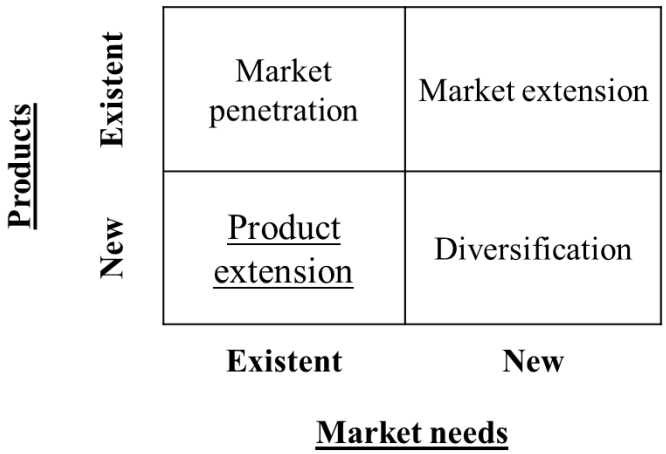

Figure 12 - Ansoff matrix

Source: Adapted from Manual de Estratégia – Conceitos, Prática e Roteiro

Nanoplex believes that is able to reduce the market share of existent and emergent alternatives due to its competitive advantage that is the effectiveness of its approach to SCLC. In addition, there is a technological gap in the market since the existent market needs are not satisfied, giving an opportunity for Nanolung to succeed.

8. Development strategy

On the previous chapters the internal and external analysis were conducted which contribute to the development of Nanoplex strategy.

Porter (1998) introduced the generic competitive strategies, the firm's relative position within its industry: cost leadership, differentiation and focus. The focus strategy has two variants cost focus and differentiation focus. These strategies result in a combination between the type of competitive advantage (lower cost or differentiation) and the competitive scope (broad target or narrow target).

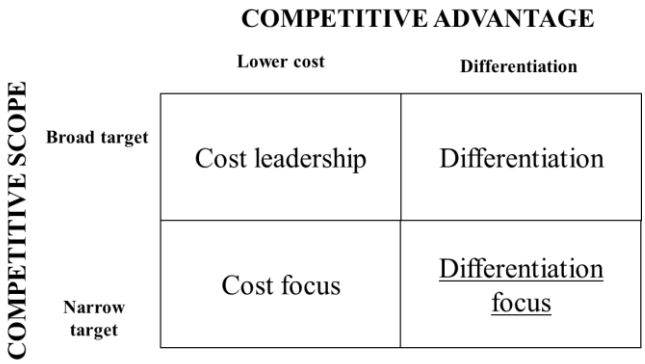

Figure 13 - Generic competitive strategies

Source: Competitive Strategy – Creating and Sustaining Superior Performance

Analyzing the generic strategies, Nanoplex will implement a differentiation focus strategy given the narrow target is been targeted, product specificities, opportunity identified and the competitive advantages mentioned.

Although Nanoplex is able to be identified with differentiation strategy, the key factor of Nanolung is the specific segment target which makes sense to opt for the focus strategy with the variant differentiation. Nanoplex achieves differentiation from better understanding and fulfillment of needs of this specific target since current solutions do not cure this type of severe cancer.

8.1 Vision, mission and values

8.1.1 Vision

At Nanoplex, we seek to deliver truly innovative solutions that help patients prevail over serious diseases as well as enhancing patients' quality of life.

8.1.2 Mission

Nanoplex mission is to be a global prestigious research and development company with an appealing pipeline of products and services for the pharmaceutical industry, while focusing in discovery and development for the treatment of cancer and other health conditions.

Make every effort to further strengthen our pipeline, maximize corporate value and contribute to the interests of each of our stakeholders.

8.1.3 Values

Nanoplex values are the following:

- **Passion for the patient** – essential to the advancement of healthcare;
- **Courage to face challenges** – continuous investment in innovation and be the pioneers of new technologies and new ways of doing business;
- **Excellence in delivering exceptional results** – highest standards in quality, encourage creativity, simplicity in problem solving as well as transparency in communicating;
- **Highest standards in integrity** – loyal and honest professionals.

8.2 Objectives and SMART goals

After defining the mission, vision and values of the company, matters to define the general objectives to be achieved, and the specific objectives (SMART) with precise goals and deadlines.

8.2.1 Objectives

- Invest on human capital growth of know-how especially in areas with lack of experience and develop an organizational culture that allows and encourage professionals to think in novelty processes;
- Attract investors to finance and promote the company's growth;
- License the technology to a well-established pharmaceutical company;
- Developing an appealing pipeline of products and services for the pharmaceutical industry.

8.2.2 SMART goals

- Implement a continuous learning plan, the CEO and CIO will attend two congresses in 2016 and three congresses in the next years. These congresses are focused on global pharmaceuticals, oncology and lung cancer such as Bio International Convention, CPhI worldwide, European Cancer Congress, AACR Annual meeting and European Lung Cancer Conference;
- Until licensing the technology, ensure 9 504 704,61€ on investment to guarantee the success of Nanolung on research and development phases;

- In 2018, one more junior researcher will be added to the internal structure of the company to face the increasingly research and development process tasks;
- By the end of 2018, Nanoplex pipeline will be increased by developing another novelty product;
- A clinical trial expert will be recruited in 2019 to ensure that all the procedures are accordingly to standards;
- In 2020, Nanoplex will start to look for a license agreement promoting the project and respective achievements through congresses (mentioned above) and roadshows with potential partners;
- License Nanolung for 1 000 000 000€, to a well-establish pharmaceutical company after clinical trial phase II (2021).

8.3 Critical success factors

Critical success factors are key activities that will determine the company' success in the industry. Additionally, these variables will allow the company to be distinguished from direct and indirect competitors. Given the importance that these factors have, it is essential to define strategies and plan activities that will ensure the Nanoplex success.

That said, Nanoplex critical success factors are:

- Investments to ensure Nanoplex continues the research and development phases and achieve the license deal;
- To patent the technology;
- Success in preliminary studies and clinical trials;
- Allocate 10% of daily working hours to develop new products and services to the pipeline;
- Define and redefine strategies taking into consideration risk planning;
- Licensing Nanolung after clinical trial phase II.

8.4 Resources, skills and strategic capability

The success of Nanoplex depends on the strategy outlined, given the resources, capabilities and strategic competences that are being offered by the company and by the product, Nanolung.

Threshold resources

- Human capital;
- Quality of raw materials and equipment;
- Efficient technology.

Unique resources

- Innovative technology;
- Patentable technology that allow exclusivity and prevent others from copying;
- Technology platform that allow the creation of more novelty products.

Threshold competences

- Professionals with scientific background;
- Develop and implement a research and development process.

Core competences

- Professionals with entrepreneurial skills;
- Doing preliminary studies and clinical trials with success;
- Communicate with the market to attract investors and pharmaceutical companies to license Nanolung by going to congresses and meetings.

Strategic capability

- Ensure investment to continue research and development tasks;
- Continuous discovery and development of products and services to present to the market an appealing pipeline;
- Ability to attract a pharmaceutical company to license Nanolung.

9. Implementation policies

The adopted Marketing-mix strategies reflect on the external and internal analysis previous developed by the author.

9.1 Product

As previously mentioned, Nanolung (figure 14), is the name chosen for the first product to be developed by the start-up company Nanoplex. The name of this treatment against small cell lung cancer was chosen due to the use of nanoparticles and the disease area, the lungs.

Figure 14 - Product logo

Source: Author

Given that Nanoplex will not commercialize the product, Nanolung is only an internal name for identification purposes. Although, it is an internal name, the licensee may opt to use it when the product reaches the market, so that the trademark is going to be protected.

As mentioned before, the Nanolung is an inhalation localized therapy, a minimal invasive approach since it goes directly to the lungs and consequently allows to avoid most of severe side effects of chemotherapy treatments.

Nanolung technology is a nanocarrier with three key functional components:

1. Antibody - ability to distinguish between healthy and cancer cells since it is specifically designed to bind to receptors found only in SCLC cells;
2. Gene therapy agent – ability to stop tumor progression and reverse the cancer stage of the cells to a point that it can be cured;
3. Anticancer drug – released into the cancer cells and kills them.

9.2 Price

From an economic point of view, the ideal price of a product covers the raw materials costs, production costs, labor costs and the company stills profits from that sell. For the consumer point of view, the ideal price is the one that maximizes satisfaction given the benefits that the product provides to the consumer, exceeding the expectations regarding the need to be satisfied.

Given that Nanoplex will make a license deal with a well establish company, the price that matters to discuss is the value of the license deal.

When defining the value of the license agreement, there are some factors to take into account. Firstly, the licensing value needs to be higher than all the costs involved in the R&D process: R&D activities, supplies and services and human resources costs that totalize 9 504 704,61€, as it can be observed in table 2 and attachment VI and VIII. Secondly, the investors that Nanoplex will raise during the following years, will need to be remunerated for the

investment done. Lastly, for validation purposes, matters to analyze licensing deals with companies with a similar structure and product.

Merck & Co were committed to pay US$200M upfront payment to Moderna Therapeutics for the license deal of Keytruda, and immunotherapy treatment. Also Bristol-Myers Squibb paid $800M as an upfront payment on a licensing deal with Flexus for their Immunotherapy treatment. Additionally to the upfront payment, US$450M are promised if development milestones are successfully achieved.

AbbVie Inc., a biopharmaceutical company, completed on June 1st of 2016, the acquisition of Stemcentrx Inc., a biotechnology company that developed Rova-T, a treatment for SCLC. AbbVie Inc., was committed to pay US$5.8B upfront payment to Stemcentrx Inc and an additional US$4B were promised if development milestones are successfully achieved. This license deal occurred before the clinical trials which represents a bigger risk of failure than if licensed after the second phase of clinical trials. Consequently, the big risk results in a lower value of the agreement.

Taking into consideration all the factors mentioned above, the value of the license agreement will be closer to the last similar company since both technologies aim the treatment of SCLC. Although AbbVie Inc. made the license deal before the clinical trials and Nanoplex intends to license after phase II of clinical trials, it must be taken into consideration the risks risk involved in Nanoplex R&D procedures of the following years as well as not being the first treatment of SCLC.

Having said that, Nanoplex expects to make a license agreement of 1 000 000 000€ (see attachment VI).

9.3 Communication

Nanoplex communication will focus on promoting the company and its product Nanolung with the aim of closing the license deal after phase II of clinical trials. These events allow to create an interesting network as well as to talk with potential investors and candidates to license the technology.

The CEO and CIO will attend two congresses in 2016 and three congresses in the next years. The projected cost of these activities were estimated with expenses per person of 2 000€ for the congress registration, 700€ for the flight ticket and 400€ for accommodation. These congresses are focused on global pharmaceuticals, oncology and lung cancer such as Bio

International Convention, CPhI worldwide, European Cancer Congress, AACR Annual meeting and European Lung Cancer Conference.

A strong network build by participating the congresses mentioned above, will allow scheduling roadshows and project presentations with potential candidates for license deals. These activities will start to take place in 2018, twice a year and in 2020 (one year before the ideal time to occur a license deal) will be performed six roadshows and project presentations.

Through the participation on congresses and meetings as well as collecting information on a daily basis regarding startup companies, licensing deals, competitor treatments of SCLC are great examples of a continuous learning process.

Additionally, before Nanoplex submits an investigational new drug application for FDA approval and since Nanolung is a treatment for an orphan disease, FDA encourages attending a pre-IND meeting to discuss development strategy estimated to occur in 2017.

10.Implementation requirements

10.1 Exit strategy

As mentioned above in the literature review chapter, the business models of pharmaceutical companies are evolving, since recent trends suggest that big pharmaceutical companies are more adequate to run operations such as product production and distribution, while start-up companies are more adequate to explore niche areas of research and development.

Also as stated in the literature review, mergers or acquisitions are often used in start-up companies due to their lack of financial resources to pursue to the market. Having said that, Nanoplex exit strategy will be licensing Nanolung to a well-establish company after clinical trials phase II.

With the licensing deal, Nanolung' credibility will increase, which will have a positive impact on the trust of doctors who will decide if their patients will use this treatment. Moreover, licensing is strategically desirable since the firm lacks of resources to establish a sustainable position and substantial market share in this competitive industry.

An example to illustrate this strategy is Nanocarrier Co ltd. It is a Japanese R&D and producer of pharmaceuticals using micellar nanoparticles technology. Their pipeline is constituted by products that are out-licensed to powerful companies with interests in areas such as health and pharmaceutics (Orient EuroPharma and Kowa).

Although Nanoplex communication plan for 2016 and beyond will promote the company and the product and consequently attracting attention for potential candidates, a more focus search for licensing partners will occur in 2020, one year before the defined time to occur the deal.

Nanoplex intends to license Nanolung after the successful completion of phase II of clinical trials, assuming that Nanoplex ensures investments until then to cover production, raw materials and human capital costs. The intention to license the technology after the completion of this phase is due to the fact that at this stage the risk of technological failure is lower and consequently Nanolung becomes a far more appealing product, allowing for an increase value on the licensing deal. After a careful and detailed financial analysis (see chapter 11), Nanolung expects to get a licensing deal of 1 000 000 000€.

10.2 Milestone map

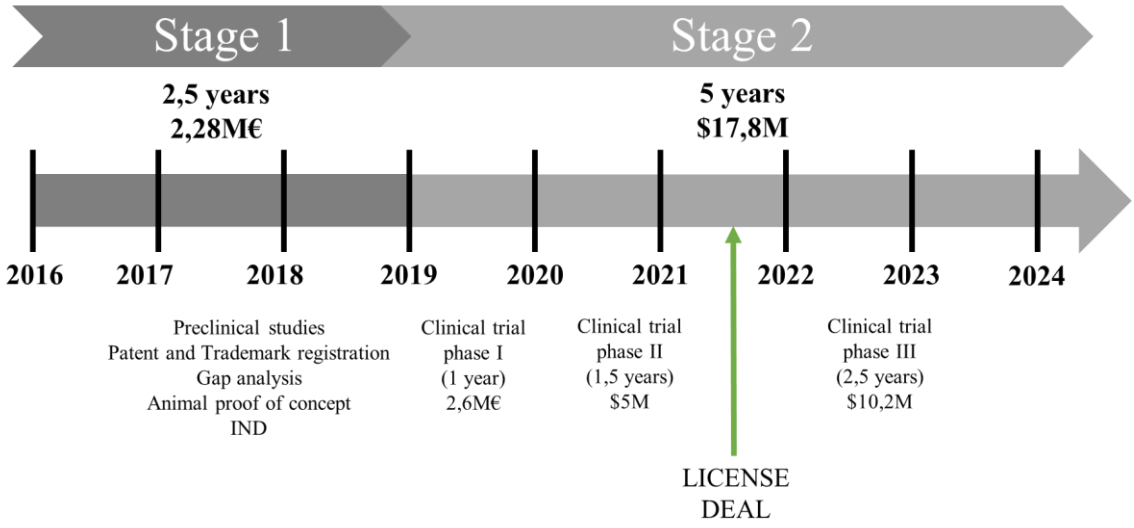

Figure 15 - Milestone map

Source: Author

At this stage Nanoplex conducted *in vitro* preliminary studies with so promising results that is ready to initiate *in vivo* studies. In order to ensure protection of all information related with Nanolung, a patent application will be submitted. Along with these activities, Nanoplex will elaborate a gap analysis, animal proof of concept and an IND application to FDA.

An IND application will be submitted with the description of all available information about the drug, such as preclinical studies (*in vitro* and *in vivo*), indicating that is reasonable to initiate clinical trial studies. In this application it will be also described detailed information regarding the initial proposed strategy for clinical trial stage.

The first stage of research and development process will take two and half years and it will have a cost of 2 280 637,71 € (see table 2 and attachment VI and VIII for details).

The second stage is clinical trials with an expected duration of 5 years and a total cost of 17 753 318,89 € (see table 2 and attachment VI and VIII for details). Since SCLC is a rare disease, the amount of time and costs related are reduced because it requires few patients in the clinical trials.

10.3 Supplies, services and equipment needed

Nanoplex requires an amount of supplies, outsourcing services and equipment to their company activities of around 94 000 € annually and 10 651,43 € for equipment (see table 2 and attachment VIII).

Regarding supplies and outsourcing services, Nanoplex will have an approximate annual cost of 94 000€ due to the office rent (that includes water and electricity), office consumables and accounting services as well as some operational daily tasks. As mentioned on SMART goals, the CEO and the CIO will participate on conferences (starting this present year, 2016) and will plan roadshows (starting in 2018). These participations include plane tickets, accommodation, trips and other expenses, and in case of conferences the registration fees per professional.

Moreover, the company will request lawyer services in order to fulfil all the legal requirements to the IP protection process. Adding to these costs, Nanoplex is required to pay IP annuities to guarantee an annual protection.

Concerning the materials being used during the R&D activities, these are not included in the supplies and services table since these can be considered an investment and therefore can be depreciated.

Given the majority of R&D studies are outsourced, Nanoplex will not make a big investment on laboratory equipment, only the essential to perform some simple but essential tests. Regarding office equipment, the company will purchase a printer and furniture in 2016 and a PC in 2017.

10.4 Implementation requisites

To successfully make a licensing deal of Nanolung with a well-establish company there are some crucial implementation requisites to be accomplished.

Firstly, the company needs to raise enough investment to face the costs mentioned above like laboratory and office resources, totalizing 10 651,43€ (see attachment VIII).

Secondly, the R&D process being a very high costly process includes two stages of development: stage 1 for preclinical studies and stage 2 including clinical trials (see table 2 and attachment VI and VIII for details). The first stage has already started and will continue until the end of 2018, with a cost of 2 280 637,71€. The second stage includes clinical trial phase I, II and III, in a total of 5 years and is estimated to cost 17 753 318,89 €. However, given that the license deal will occur after the clinical trial phase II, the costs of phase III, totalizing 10 200 000 €, are not included,.

Lastly, the patent protection represents an enormous investment to Nanoplex (see attachment VIII). The patent protection involves the costs of lawyer services as well as annuities to maintain the patent protection. Also, Nanoplex will register a trademark protection to the name of the product, Nanolung. The trademark registration will occur in 2017 and it will have a cost of 295 € (see attachment VIII) and will also require lawyer services. In order to keep a trademark protection, Nanoplex will need to pay 90 € for the maintenance filling in 2022 and 364 € for renewal 10 years after the registration, in 2027. Since the trademark' maintenance and renewal will occur after 2021 (last year accounted in the financial projections), these costs will not be observed in the chapter 11.

10.5 Risk planning

A new entrant's ability to stay alive in the healthcare industry's highly regulated environment is dependent on how effectively it can incorporate, embrace, and manage the appropriate risks as part of organizational strategies, operations and processes. Maintaining an effective compliance program protects brand reputation and value by enabling crisis prevention, management and remediation.

In a tech-based start-up, a technology without IP protection is a risk that should be managed by defining strategies to mitigate this risk. In view of this, a patent application will be submitted with detailed information regarding the characteristics of the technology as well as its use. So far, the technology has been kept a trade secret, without any disclosure in scientific papers or other forms of communication allowing the correct and most protecting patent application.

Moreover, since Nanolung is still a product under development, there are technological risks associated namely unsuccessful results in tests. To ensure success in all stages of research and development it is essential to define an adequate product development process. *In vitro* preliminary studies have already been performed and promising results indicate that it is reasonable to start *in vivo* studies. Afterwards, clinical studies will be conducted to understand the full potential of this technology and above all to prove that the technology does not have any side effects to human beings.

Nanoplex human capital has only a scientific background and lacks of business and entrepreneurial experience, which constitutes a risk to the start-up company. For that reason, a CEO with business experience will be recruited in 2016. Additionally the CEO and CIO will attend congresses focused on global pharmaceuticals, oncology and lung cancer such as Bio International Convention, CPhI worldwide, European Cancer Congress, AACR Annual meeting and European Lung Cancer Conference. By attending to congresses, Nanoplex develops a strong network with future investors, reducing the risk of lack of financial resources that are required in order to perform R&D operations until the license agreement. Also, this strong network allows scheduling roadshows and project's presentations that aim to attract potential candidates for the licensing agreement.

11.Financial forecasts

Financial forecasts are pivotal for business plans given it will answer to the research question, ***Is Nanolung, a treatment against Small Cell Lung Cancer, economically and financially viable?***

In order to elaborate these financial forecasts, the author will explain all the assumptions that based the forecasting process.

Since Nanoplex will not commercialize Nanolung, the financial forecasts were made until the year 2021, the year that the company will make a licensing deal with a well establish pharmaceutical company.

11.1 Assumptions

Bearing in mind the external environment, financial forecasts were made based on the assumptions shown in attachment V. The author used information from official governmental and public sources, guaranteeing the accuracy of the results achieved.

Having said that, the assumptions to be acknowledged are:

- The financial forecasts will be made until 2021, the year that Nanolung will be licensed;
- The predicted inflation rates will be 1.34% in 2017, 1.55% in 2018, 1.70% in 2019, 1.78% in 2020 (Statista, 2016) and the author assumes an inflation rate of 2% in 2021 based on the growing trend shown in the years before;
- The increasing rate in wages was defined to be above the inflation rate. Thus, the wages will have an increasing rate of 2% between the period 2017-2020 and 2.5% in 2021;
- The interest rate of the treasury bill (10 years period) of the Portuguese government is 3.06% (Banco de Portugal, 2016);
- The VAT rate applied to purchases of raw materials and supplies and service expenses and in sales is considered 23% (Economias, 2016);
- Both account receivables period and account payables period are 30 days;
- The average inventory period is 30 days, as well as the period of paying or receiving VAT, social security taxes or the tax withholding period;
- The company needs to pay an average tax rate on profits of 17% (Economias, 2016) and a balance local state tax of 1.5% (Portal das Finanças, 2016), which equals to 18.5% of taxes on profits;
- Nanoplex pays 23.75% of the employee wage to social security, while the employee pays 11%, which is withheld by the company (Segurança Social, 2016);
- Each employee pays an average income tax of 14.5% over his salary, which is withheld by the company (Economias, 2016);
- Nanoplex pays 1% over each employee wage as accidents insurance;
- Each employee is entitled to receive a food allowance of 4.27€ per day (Economias, 2016);
- In 2021, the company will distribute 2% of the licensing agreement to its workers, as a variable salary;
- Nanoplex is funded with almost 100% of equity and some short-run debt, and it will use both debt and equity during the development phase to finance their activities;
- Pharmaceutical industry is characterized by a cost of equity of 8.37%, a cost of debt of 4.52% and a β of 1.02 (Damodaran, 2016);
- It is consider a short-run financing interest rate of 3%;

- It will not be calculated the continuation value of the project since there will be a licensing agreement in 2021.

11.2 Financial forecasts for Nanoplex

11.2.1 Cost projections

The author will not perform any sales projection, since Nanoplex will not commercialize Nanolung. As result, the company will not have any cost of goods sold, therefore it will be only projected the forecast of supplies and services expenses.

Costs of Goods Sold and Supplies and Services Expenses - Current Prices						
	2016	2017	2018	2019	2020	2021
Accumulated Inflation Factor	1,000	1,013	1,029	1,047	1,065	1,087
Supplies and Services Expenses Unit Cost	0	1	2	3	4	5
Office Rent	18 000,00 €	18 241,20 €	18 523,94 €	18 838,85 €	19 174,18 €	19 557,66 €
Accounting services	7 000,00 €	7 093,80 €	7 203,75 €	7 326,22 €	7 456,62 €	7 605,76 €
Roadshows	- €	- €	4 528,07 €	4 605,05 €	4 687,02 €	14 342,28 €
Conferences	12 400,00 €	18 849,24 €	19 141,40 €	19 466,81 €	19 813,32 €	20 209,58 €
Office Consumables	5 000,00 €	5 067,00 €	5 145,54 €	5 233,01 €	5 326,16 €	5 432,68 €
IP Annuities	15 000,00 €	18 241,20 €	36 018,77 €	52 330,13 €	63 913,92 €	38 028,78 €
Lawyer fees	8 000,00 €	8 107,20 €	- €	- €	- €	- €
Total SSE Purchases	65 400,00 €	75 599,64 €	90 561,48 €	107 800,06 €	120 371,22 €	105 176,75 €

Table 2 - COGS and supplies and services expenses

Source: Author

11.2.2 Investment in net working capital

NET WORKING CAPITAL - CURRENT PRICES, Y0							
	Period	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
FIRM'S NEEDS							
Account's Receivables	**30**						
Stocks	**30**	- €	- €	- €	- €	- €	- €
Vat to Receive	**30**	13 623,15 €	14 239,74 €	3 268,33 €	44 575,81 €	85 643,78 €	- €
TOTAL NEEDS OF THE FIRM		**13 623,15 €**	**14 239,74 €**	**3 268,33 €**	**44 575,81 €**	**85 643,78 €**	**- €**
FIRM'S RESOURCES							
Account payables	**30**	5 375,34 €	6 213,67 €	7 443,41 €	8 860,28 €	9 893,53 €	8 644,66 €
GOPE (SS)	**30**	4 423,76 €	4 512,24 €	5 268,29 €	5 373,66 €	5 481,13 €	626 283,64 €
GOPE (Income Taxes)	**30**	1 845,89 €	1 882,81 €	2 198,28 €	2 242,25 €	2 287,09 €	261 326,99 €
TOTAL RESOURCES OF THE FIRM		**11 644,99 €**	**12 608,71 €**	**14 909,98 €**	**16 476,18 €**	**17 661,75 €**	**896 255,29 €**
NEEDS OF NET WORKING CAPITAL		**1 978,16 €**	**1 631,03 €**	**- 11 641,65 €**	**28 099,62 €**	**67 982,04 €**	**- 896 255,29 €**
INVESTMENT IN NET WORKING CAPITAL		**1 978,16 €**	**- 347,13 €**	**- 13 272,68 €**	**39 741,27 €**	**39 882,41 €**	**- 964 237,33 €**

Table 3 - Net working capital

Source: Author

Given Nanoplex will not have any commercial activity, the account of stocks and the account's receivables are zero and the value that Nanoplex will receive in VAT is low. This value will increase in 2019 and in 2020 due to the high investments in R&D that the company needs to make.

11.2.3 Cash flow analysis

CASH FLOW STATEMENT - CURRENT PRICES						
	2016	2017	2018	2019	2020	2021
FINANCIAL RESOURCES						
NOPAT	- 262 752,15 €	- 276 816,16 €	- 325 833,76 €	- 348 707,79 €	- 365 973,11 €	863 663 104,40 €
Uninvestment in NWC	- €	347,13 €	13 272,68 €	- €	- €	964 237,33 €
TOTAL FINANCIAL RESOURCES	**- 262 752,15 €**	**- 276 469,04 €**	**- 312 561,08 €**	**- 348 707,79 €**	**- 365 973,11 €**	**864 627 341,73 €**
FINANCIAL NEEDS						
Investment in Assets	655 244,94 €	677 662,09 €	82 328,62 €	2 250 195,44 €	4 410 060,71 €	- €
Investment in NWC	1 978,16 €	- €	- €	39 741,27 €	39 882,41 €	- €
TOTAL FINANCIAL NEEDS	**657 223,10 €**	**677 662,09 €**	**82 328,62 €**	**2 289 936,71 €**	**4 449 943,12 €**	**- €**
CASH FLOW OF THE PROJECT	**- 919 975,24 €**	**- 954 131,13 €**	**- 394 889,70 €**	**- 2 638 644,50 €**	**- 4 815 916,23 €**	**864 627 341,73 €**
ACCUMULATED CASH FLOW	**- 919 975,24 €**	**- 1 874 106,37 €**	**- 2 268 996,07 €**	**- 4 907 640,57 €**	**- 9 723 556,80 €**	**854 903 784,93 €**

Table 4 - Cash flow statement

Source: Author

Nanoplex will have to invest in NWC in 2016, 2019 and 2020 for funding the huge investments the company will have to bear. On the other hand, in 2017, 2018 and in 2021 investments in NWC will not be made, resulting in an improvement of the cash flows. Consequently, in 2021, after the licensing deal, and beyond the company will only have positive cash flows.

11.2.4 Economic evaluation of the project

ECONOMIC EVALUATION OF THE PROJECT						
PROJECT'S EVALUATION	**0**	**1**	**2**	**3**	**4**	**5**
Cash Flow of the Project	- 919 975,24 €	- 954 131,13 €	- 394 889,70 €	- 2 638 644,50 €	- 4 815 916,23 €	864 627 341,73 €
Accumulated Inflation Factor	**1,0000**	**1,0134**	**1,0291**	**1,0466**	**1,0652**	**1,0865**
Deflated Cash Flow	- 919 975,24 €	- 941 514,83 €	- 383 720,48 €	- 2 521 152,42 €	- 4 521 001,98 €	795 764 509,44 €
WACC	**8,57%**	**11,23%**	**8,57%**	**16,92%**	**16,68%**	**8,57%**
Discount Factor	1,0000	1,1123	1,2076	1,4119	1,6473	1,7885
Discounted Cash Flow	- 919 975,24 €	- 846 476,76 €	- 317 761,31 €	- 1 785 662,68 €	- 2 744 459,23 €	444 943 447,52 €
Accumulated Discounted Cash Flow	- 919 975,24 €	- 1 766 452,00 €	- 2 084 213,31 €	- 3 869 875,99 €	- 6 614 335,23 €	438 329 112,30 €
Net Present Value of the Project	438 329 112,30 €					
Internal Rate of Return	261,46%					
Payback Period of Project	5,01					

Table 5 - Project's evaluation

Source: Author

The method used to evaluate the project is the DCF (discounted cash flow), the most used method in technological-base start-ups and in the pharmaceutical industry. The net present value consists on the cumulative value of the discounted cash flows of the company, a pivotal criterion to present to future investors. The value 438 329 112,30€, allows to conclude that this project is worth of investment.

11.2.5 Provisional income statement

INCOME STATEMENT - CURRENT PRICES						
	2016	**2017**	**2018**	**2019**	**2020**	**2021**
Sales						1 086 536 697,07 €
Costs of Goods Sold						
Gross Margin	**- €**	**- €**	**- €**	**- €**	**- €**	**1 086 536 697,07 €**
External Services and Supplies	65 400,00 €	75 599,64 €	90 561,48 €	107 800,06 €	120 371,22 €	105 176,75 €
Personnel Costs	197 352,15 €	201 216,52 €	235 272,28 €	240 907,73 €	245 601,88 €	27 360 677,52 €
EBITDA	**- 262 752,15 €**	**- 276 816,16 €**	**- 325 833,76 €**	**- 348 707,79 €**	**- 365 973,11 €**	**1 059 070 842,80 €**
EBITDA margin						97%
Depreciations and Amortizations	33 710,79 €	67 710,59 €	95 150,72 €	207 660,49 €	428 026,23 €	400 455,64 €
EARNINGS BEFORE TAXES	**- 296 462,94 €**	**- 344 526,76 €**	**- 420 984,48 €**	**- 556 368,28 €**	**- 793 999,34 €**	**1 058 670 387,16 €**
Deductible Losses	- €	- 296 462,94 €	- 640 989,69 €	- 1 061 974,17 €	- 1 618 342,46 €	- 2 412 341,79 €
Taxable Amount	- 296 462,94 €	- 640 989,69 €	- 1 061 974,17 €	- 1 618 342,46 €	- 2 412 341,79 €	1 056 258 045,36 €
Taxes on Profits	- €	- €	- €	- €	- €	195 407 738,39 €
NET INCOME	**- 296 462,94 €**	**- 344 526,76 €**	**- 420 984,48 €**	**- 556 368,28 €**	**- 793 999,34 €**	**863 262 648,76 €**
NOPAT	**- 262 752,15 €**	**- 276 816,16 €**	**- 325 833,76 €**	**- 348 707,79 €**	**- 365 973,11 €**	**863 663 104,40 €**

Table 6 - Income statement

Source: Author

In the income statement herewith presented, matters to enhance and explain the difference of sales between 2020 and 2021. The value of 1 086 536 697,07 € is the value of the licensing deal at current prices.

11.2.6 Financial plan

FINANCIAL PLAN - CURRENT PRICES							
		2016	2017	2018	2019	2020	2021
FINANCIAL RESOURCES							
EBITDA		- 262 752,15 €	- 276 816,16 €	- 325 833,76 €	- 348 707,79 €	- 365 973,11 €	1 059 070 842,80 €
Uninvestment in NWC		- €	347,13 €	13 272,68 €	- €	- €	964 237,33 €
Shared Capital		1 000 000,00 €	- €	- €	- €	- €	- €
Other Equity Instruments		- €	411 643,08 €	2 058 215,40 €	- 2 469 858,48 €	411 643,08 €	2 058 215,40 €
Financial Aplication Recovery		- €	- €	- €	1 178 923,84 €	- €	- €
Return of Financial Apllications		- €	- €	- €	17 683,86 €	- €	- €
TOTAL FINANCIAL RESOURCES		**737 247,85 €**	**135 174,04 €**	**1 745 654,32 €**	**- 1 621 958,57 €**	**45 669,97 €**	**1 062 093 295,52 €**
FINANCIAL NEEDS							
Investment in Assets		655 244,94 €	677 662,09 €	82 328,62 €	2 250 195,44 €	4 410 060,71 €	- €
Investment in NWC		1 978,16 €	- €	- €	39 741,27 €	39 882,41 €	- €
Payout		- €	- €	- €	- €	- €	- €
GOPE - Taxes on Profits		- €	- €	- €	- €	- €	- €
Reimbursment of Short-run Financial Applications		- €	- €	483 172,12 €	- €	4 037 715,12 €	8 704 145,89 €
Taxes on Profits of Financial Applications		- €	- €	- €	3 271,51 €	- €	- €
TOTAL FINANCIAL NEEDS		**657 223,10 €**	**677 662,09 €**	**565 500,74 €**	**2 293 208,23 €**	**8 487 658,24 €**	**8 704 145,89 €**
TARGETED VALUE	**30**	**80 024,76 €**	**6 213,67 €**	**7 443,41 €**	**8 860,28 €**	**9 893,53 €**	**8 644,66 €**
VALUE TO FINANCE		**- €**	**468 676,96 €**	**- €**	**3 916 583,67 €**	**8 443 021,52 €**	**- €**
VALUE TO APPLY		**- €**	**- €**	**1 178 923,84 €**	**- €**	**- €**	**1 053 390 398,49 €**
Short-Run Financing		- €	483 172,12 €	- €	4 037 715,12 €	8 704 145,89 €	- €
Interests of Short-Run Financing		- €	14 495,16 €	- €	121 131,45 €	261 124,38 €	- €
CASH AND EQUIVALENTS		**80 024,76 €**	**- 73 811,09 €**	**1 229,74 €**	**1 416,87 €**	**1 033,25 €**	**- 1 248,86 €**
CUMULATIVE CASH		**80 024,76 €**	**6 213,67 €**	**7 443,41 €**	**8 860,28 €**	**9 893,53 €**	**8 644,66 €**

Table 7 - Financial plan

Source: Author

11.2.7 Provisional balance sheet

BALANCE SHEET - CURRENT PRICES						
	2016	2017	2018	2019	2020	2021
ASSETS						
Non-current Assets						
Intangible Assets						
R&D Expenses	612 750,00 €	580 500,00 €	603 138,49 €	2 681 134,03 €	6 698 491,81 €	6 333 359,46 €
Industrial property	- €	643 387,65 €	609 525,14 €	575 662,63 €	541 800,12 €	507 937,61 €
Sub-Total	**612 750,00 €**	**1 223 887,65 €**	**1 212 663,63 €**	**3 256 796,66 €**	**7 240 291,93 €**	**6 841 297,08 €**
Tangible Assets						
Laboratory Equipment	8 572,00 €	7 144,00 €	5 716,00 €	4 288,00 €	2 860,00 €	1 432,00 €
Administrative Equipment	212,15 €	454,00 €	283,92 €	113,83 €	81,04 €	48,25 €
Sub-Total	**8 784,15 €**	**7 598,00 €**	**5 999,92 €**	**4 401,83 €**	**2 941,04 €**	**1 480,25 €**
Current Assets						
Inventory	- €	- €	- €	- €	- €	- €
Account Receivables	- €	- €	- €	- €	- €	- €
GOPE	13 623,15 €	14 239,74 €	3 268,33 €	44 575,81 €	85 643,78 €	- €
Financial applications	- €	- €	1 178 923,84 €	- €	- €	1 053 390 398,49 €
Cash and Equivalents	80 024,76 €	6 213,67 €	7 443,41 €	8 860,28 €	9 893,53 €	8 644,66 €
Sub-Total	**93 647,91 €**	**20 453,41 €**	**1 189 635,58 €**	**53 436,08 €**	**95 537,31 €**	**1 053 399 043,16 €**
TOTAL DAS ASSETS	**715 182,06 €**	**1 251 939,06 €**	**2 408 299,13 €**	**3 314 634,57 €**	**7 338 770,28 €**	**1 060 241 820,49 €**
EQUITY						
Shared Capital	1 000 000,00 €	1 000 000,00 €	1 000 000,00 €	1 000 000,00 €	1 000 000,00 €	1 000 000,00 €
Other Equity Instruments	- €	411 643,08 €	2 469 858,48 €	- €	411 643,08 €	2 469 858,48 €
Reserves	- €	- €	- €	- €	- €	50 000,00 €
Reserves and Retained Earnings	- €	- 296 462,94 €	- 655 484,86 €	- 1 076 469,34 €	- 1 739 556,73 €	- 2 794 680,44 €
Retained Earnings	- 296 462,94 €	- 359 021,92 €	- 420 984,48 €	- 663 087,39 €	- 1 055 123,71 €	433 015 364,07 €
Payout	- €	- €	- €	- €	- €	430 270 683,63 €
TOTAL EQUITY	**703 537,06 €**	**756 158,22 €**	**2 393 389,14 €**	**- 739 556,73 €**	**- 1 383 037,36 €**	**864 011 225,74 €**
LIABILITIES						
Long Run Liabilities						
Bank Loans	- €	- €	- €	- €	- €	- €
Sub-Total	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**
Short Run Liabilities						
Account Payables	5 375,34 €	6 213,67 €	7 443,41 €	8 860,28 €	9 893,53 €	8 644,66 €
GOPE	6 269,65 €	6 395,04 €	7 466,57 €	7 615,90 €	7 768,22 €	887 610,63 €
Taxes on Profits	- €	- €	- €	- €	- €	195 334 339,46 €
Bank Loans						
Bank Loans in Euros	- €	- €	- €	- €	- €	- €
Short-Run Financing	- €	483 172,12 €	- €	4 037 715,12 €	8 704 145,89 €	- €
Sub-Total	**11 644,99 €**	**495 780,84 €**	**14 909,98 €**	**4 054 191,30 €**	**8 721 807,64 €**	**196 230 594,75 €**
TOTAL LIABILITIES	**11 644,99 €**	**495 780,84 €**	**14 909,98 €**	**4 054 191,30 €**	**8 721 807,64 €**	**196 230 594,75 €**
TOTAL EQUITY AND LIABILITES	**715 182,06 €**	**1 251 939,06 €**	**2 408 299,13 €**	**3 314 634,57 €**	**7 338 770,28 €**	**- €**

Table 8 - Balance sheet

Source: Author

11.2.8 Sensitivity analysis

Sensitivity analysis is an important technique since it allows determining how different values of an independent variable impact a particular dependent variable under a given set of assumptions.

Given the exit strategy of Nanoplex is licensing the technology, the major financial risk for the investors is the value (and its variation) of the license agreement as well as understanding the impact that these variations have to the company's performance.

The table 9 shows the variations calculated for the licensing deal. It was consider a negative variation of 20% of the licensing value for the pessimist scenario and a positive variation of 20% in the positive scenario. These variations reflect the competitive environment of the pharmaceutical industry. Even considering a negative variation of 20% the NPV still indicates Nanolung is worth of the investment.

Scenarios	Actual	Pessimistic	Optimistic
Variable Cells		< 20%	> 20%
Licence deal	1 000 000 000 €	800 000 000 €	1 200 000 000 €
Results Cells			
NPV	438 329 112,30 €	349 372 760,12 €	527 285 464,47 €
IRR	261,46%	244,08%	276,19%
Payback	5,01	5,02	5,01

Table 9 - Sensitivity analysis

Source: Author

11.2.9 Ratios

Financial ratios allow investors to acknowledge the performance of Nanoplex. The company will only generate profits after the licensing deal, in 2021. Therefore, it is paramount to understand how the licensing deal will affect the company performance and if it reflects as a viable or not viable project. Having said that, the following rations will quantify the situation of Nanoplex after the licensing deal.

Economic Ratios	2021
Return On Investment (ROI)	81%
Return on Assets (ROA)	100%
Return on Equity (ROE)	100%

Table 10 - Economic ratios

Source: Author

Regarding the economic ratios, a ROI of 81% means that each euro invested in this company, will have a return of 0,81€ to the investors. Moreover, 100% of ROA, indicates that each euro hold in the assets of the company will generate 1€ in return. Lastly, 100% of ROE means that each euro invested in the company by shareholders, it will have a return of 1€ in the end of 2021. Given Nanoplex only generated profits in 2021, these rations where only calculated on that year.

Financial Ratios	**2021**
Equity Ratio	81%
Debt-to-Equity Ratio	23%

Table 11 - Financial ratios

Source: Author

Financial ratios represents the financial health of a company. An equity ratio relates equity with total assets, indicating the level of leverage used by a company. An equity ratio of 81% means that, 81% of the assets are financed by equity, resulting in a company low dependence of bank loans and other debt instruments. Additionally, debt-to-equity ratio indicates as well the leverage of the company. A debt-to-equity of 23% represents how much debt Nanoplex is using to finance its assets, so it can be concluded that the company is using a relatively small amount, which reflects the fact that the major part of the funds needed are going to be provided by equity.

Liquidity Ratios	**2021**
Current Ratios	537%

Table 12 - Liquidity ratios

Source: Author

Lastly, the liquidity ratio demonstrates the capacity that Nanoplex has to pay its liabilities. The current ratio relates the current assets and current liabilities. Nanoplex has five times more assets than liabilities, meaning that the company has the capacity to meet all the short-run liabilities with the current assets.

12. Conclusion

This business plan allows to affirm that Nanolung, a treatment against SCLC, is economical and financial viable. After the conclusion of all the analysis it is pivotal to enhance some aspects mentioned in this business plan.

The pharmaceutical industry is characterized by its significant competition from many pharmaceutical and research and development companies. Nanoplex, suits to the type of companies that will only focus on R&D activities due to strong scientific background, poor distribution systems and lack of financial resources. On the other hand, well-established pharmaceutical companies have large expertise in preclinical and clinical trials as well as obtaining regulatory approvals for drugs. In a nutshell, mergers and acquisitions of startup companies to well-establish pharmaceutical companies are beneficial to both parts.

Moreover, Nanoplex internal structure has a scientific background that allows the company to continue to develop more products to add to the pipeline. In this sense, the company will continue to follow an adequate strategy since it will focus on its core competences.

In the light of the above, the licensing deal is crucial for the success of Nanoplex. After closing the patent sale, Nanoplex needs to cover all the costs generated as well as pay the compensation agreed previously with the initial investors.

To conclude, the financials allow to supporting that Nanolung is economical and financial viable; with an NPV of 438 329 112,30€, an internal rate of return of 261,46% and a payback period of five years and four days.

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14. Appendices

Attachment I - Interview script

1. Taking into consideration the complexity of the pharmaceutical industry and the intended future development of Nanoplex, do you agree that the most adequate exit strategy is to license the technology to a well-establish pharmaceutical company?
2. If the license deal occurs after the completion of clinical trials phase II and given the risk of product fail is reduced, will the value of the license deal increase?
3. Nanolung, is a treatment against small cell lung cancer with pulmonary administration. Given the specificities of this treatment, which R&D tests should be privileged for a smoother registration process and what are the costs involved?
4. Regarding human capital, how many employees should the company have and what is the current labor market price for each category?
5. Given most of the R&D tests are performed through outsourcing, is it necessary the acquisition of laboratory equipment? If yes, what would be the most critical?
6. What are and how much are the costs involved with the patent application? Both for getting it and to maintain it along its life.
7. What is the method of evaluation of the license deal currently used in the pharmaceutical industry?

Attachment II – Ana Gonçalves curriculum vitae

Consultant for the pharmaceutical industry

PERSONAL INFORMATION:

Name: Ana Maria Marques Gonçalves

Born: 26th August, 1948 in Lisbon, Portugal

Phone number: 919207950

Email: anagoncalves1948@gmail.com

EDUCATION:

1967 finished secondary school, grade 17

1971 Bachelor degree in Engineering Chemistry, grade 15

1989 Pharmaceutical administration course, Universidade Internacional

CAREER:

Currently

- Reformed since January 2014
- Consultant for the pharmaceutical industry specialized in FDA inspections and CQ optimization processes
- Cohitec mentor

2011/2013 Hovione FarmaCiencia SA

Senior fellow drug product development

Make all technical support for inhalation, oral and devices projects developed

Have responsibilities for the sourcing and acquisitions of all development and clinical manufacturing equipment

AIFs and CapEx responsibility

Provide all inhalation and oral assessments for new projects

Responsible of the installations for the manufacture of the formulation development in terms of safety and quality

2008/2011 Hovione FarmaCiencia SA

Principal scientist pharma operations

Development of inhaled DPI and oral formulation (PoC, feasibility tests, DoE studies for improve formulations and respective stability studies)

Development of inhaled DPI devices

Development and validation of all analytical methods needs for analyse DPI and oral formulations

GMP production and analyse of batches for phase !, 2a and 2b

2004/2008 Hovione FarmaCiencia SA

Director of pharma operations

Budget planning and monitoring

Recruit team members to the group, help define objectives and develop plans

Balance workload between team members

Lead a development group for the following work

Development of inhaled DPI formulation (POC, feasibility tests, DoE studies for improve formulations and respective stability studies)

Development of inhaled DPI devices

Development and validation of all analytical methods needs for analyze DPI formulations

GMP production and analyses of batches for phase 1, 2a and 2b

1992/2004 Hovione FarmaCiencia SA

Director of analysis and quality control group

Budget planning and monitoring

Recruit team members to the group, help define objectives and development of plans

Balance workload between team members

All GMP documentations

External and internal auditing

All QC work in API release

Stability work in accordance ICH guidelines

Developed and validation of analytical methods (GC, HPLC, PSD, IC, GC/MS, HPLC/MS, etc)

1980/1992 STERLING WINTHROP, produtos farmacêuticos, Lda

Director of quality control, quality assurance and technical service

Organization and management of the department

External and internal auditing

Personnel training

Make proof of concept studies in new pharmaceutical formulations

Improvement of actual formulation

1977/1980 STERLING WINTHROP, produtos farmacêuticos, Lda

Head of section Raw materials and final products

Personnel supervision

Development and validation of analytical methods (HPLC, GC) for raw materials and drug products

1971/1977 STERLING WINTHROP, produtos farmacêuticos, Lda

Analysis technician

Raw materials and finished products analysis (tablets, capsules, sachets, syrups, nasal drops, injectable, etc)

Affiliations:

2001/2005 Expert for European pharmacopoeia (antibiotic group)

Awards:

9/2013 First patent registered

9/2012 Hovione innovation prize

2/2012 Hovione innovation award

5/2011 Hovione innovation award

7/2010 Hovione innovation awards

1998 Best factory in terms of quality, Sterling Winthrop, produtos farmacêuticos, lda

1983 Quality assurance manager of the year, Sterling Winthrop, produtos farmacêuticos, lda

Attachment III – António Dinis curriculum vitae

Experience

2014-Present Director of marketing & communication at Hovione

2009-Present Executive consultant at COTEC Portugal

2008-Present Volunteer at Junior Achievement Portugal

2011-2014 Commercial manager at iMAX diagnostic imaging Ldt

2011-2014 Business development manager at Hovione

2007-2011 Account manager at Hovione

2006-2007 Consultant at Portuguese health ministry

2001-2005 Supply chain and IT manager at DSM

Education

Universidade Nova de Lisboa

MBA, Business administration, 2005-2006

Universidade Nova de Lisboa

MSc, Biotechnology, 1991-1997

Attachment IV – Porter five forces quantitative table

Threat of new entrants	Weight	Present	Future
Barriers to entry			
Economies of scale gained by main players	0,5	0,5	0,5
Product differentiation	0,5	0,25	0,26
Cost inequity	0,5	0,1	0,1
Customer switching costs	0,5	0,1	0,1
Main players'costs or quality advantages	0,5	0,5	0,5
Access to distribution channels	0,5	0,2	0,2
Government policy restrictions	0,5	0,5	0,5
Expected retaliation			
Availability of resources to fight back the entrants attack	0,5	0,1	0,1
Competitors willingness to cut prices	0,5	0,1	0,1
Industry growth	0,5	0,5	0,5
Total	5	2,85	2,86

Table 13 - Threat of new entrants

Source: Author

Rivalry among existing competition	Weight	Present	Future
Number of equal (in size and power) competitors	0,8	0,7	0,8
Industry growth	0,8	0,8	0,8
Product differentiation	0,6	0,3	0,4
Magnitude of capacity expansion required	0,6	0,5	0,5
Exit barriers	0,7	0,5	0,5
Diversity of rivals	0,75	0,75	0,75
Threat of horizontal integration	0,75	0,75	0,75
Total	5	4,3	4,5

Table 14 - Rivalry among existing competition

Source: Author

Bargaining power of suppliers	Weight	Present	Future
Number of suppliers	1	0,5	0,5
Level of supplier concentration	1	0,3	0,3
Switching costs in changing a supplier	0,75	0,4	0,4
Differentiation of purchased resources	0,75	0,3	0,3
Importance of industry for supplier	0,75	0,3	0,3
Potential threat of forward integration	0,75	0,6	0,6
Total	5	2,4	2,4

Table 15 - Bargaining power of suppliers

Source: Author

Bargaining power of buyers	Weight	Present	Future
Number of buyers	1	1	1
Level of buyer concentration	1	0,1	0,1
Level of buyers sophistication	1	0,5	0,5
Buyers' switching costs	0,5	0,1	0,1
Buyers price sensitivity	0,5	0,4	0,4
Importance of the products or services quality for the buyers	0,5	0,5	0,5
Proportion of industry product purchase in buyers' expenditures struture	0,25	0,2	0,2
Potential threat of backward integration	0,25	0,01	0,01
Total	5	2,81	2,81

Table 16 - Bargaining power of buyers

Source: Author

Threat of substitute products or services	Weight	Present	Future
Number of substitutes	1,25	0,75	0,75
Obvious advantage of substitute	1,25	0,75	0,75
Buyers' switching costs to the substitute	1,25	1	1
Profitability level of industries offering substitutes	1,25	1	1
Total	5	3,5	3,5

Table 17 - Threat of substitute products or services

Source: Author

Attachment V – Assumptions

Interest Rate Treasury bills 10 years	3,06%
Short-Run Financing Interest Rate	3,00%
Short-Run Financial Applications Interest Rate	1,50%
Average Income Taxes	14,50%
Social Security Rate (Employees)	11,00%
Social Security Rate (Firms)	23,75%
Workers Accidents Insurance	1,00%
Food Allowance (4,27/day)	93,94 €
Balance Local State Tax	1,50%
Average Tax Rate	17,00%
Taxes on Profits	18,50%
Payout	50,00%
VAT undertaken to State	23,00%
VAT Payed Tax	23,00%
EUR/USD Exchange Rate	$ 1,10

Table 18 - Assumptions 1

Source: Author

Average Inventory Period	30
Account Receivables Period	30
Account Payables Period	30
Account Receivables/Payables VAT	30
Account Payables Period (Social Security)	30
Account Payables Period (Employees Income Taxes)	30
Net Working Capital Period	30

Table 19 - Assumptions 2

Source: Author

Attachment VI – Personnel costs

Personnel Costs - Current Prices							
		2016	**2017**	**2018**	**2019**	**2020**	**2021**
		0	**1**	**2**	**3**	**4**	**5**
Accumulated Factor of Wages Increase		**1,000**	**1,020**	**1,040**	**1,061**	**1,082**	**1,109**
Staff							
CEO		1	1	1	1	1	1
CIO		1	1	1	1	1	1
Senior researcher		1	1	1	1	1	1
Junior researcher		1	1	2	2	2	2
Clinical trial expert		0	0	0	1	1	1
Total Staff		**4**	**4**	**5**	**6**	**6**	**6**
Average Monthly Salary							
CEO	€ 3 850,43	€ 3 850,43	€ 3 927,44	€ 4 005,99	€ 4 086,11	€ 4 167,83	€ 4 272,02
CIO	€ 3 390,48	€ 3 390,48	€ 3 458,29	€ 3 527,46	€ 3 598,00	€ 3 669,96	€ 3 761,71
Senior researcher	€ 2 221,86	€ 2 221,86	€ 2 266,30	€ 2 311,62	€ 2 357,86	€ 2 405,01	€ 2 465,14
Junior researcher	€ 1 600,43	€ 1 600,43	€ 1 632,44	€ 1 665,09	€ 1 698,39	€ 1 732,36	€ 1 775,67
Clinical trial expert	€ 3 707,58	€ 3 707,58	€ 3 781,73	€ 3 857,37	€ 3 934,51	€ 4 013,20	€ 4 113,53
Average Annual Salary							
CEO		€ 53 906,02	€ 54 984,14	€ 56 083,82	€ 57 205,50	€ 58 349,61	€ 59 808,35
CIO		€ 47 466,72	€ 48 416,05	€ 49 384,38	€ 50 372,06	€ 51 379,50	€ 52 663,99
Senior researcher		€ 31 106,04	€ 31 728,16	€ 32 362,72	€ 33 009,98	€ 33 670,18	€ 34 511,93
Junior researcher		€ 22 406,02	€ 22 854,14	€ 46 622,45	€ 47 554,90	€ 48 505,99	€ 49 718,64
Clinical trial expert							
Total costs with wages		**€ 154 884,80**	**€ 157 982,50**	**€ 184 453,37**	**€ 188 142,44**	**€ 191 905,29**	**€ 196 702,92**
Variable Salaries (on licensing agreement)	2%						€ 21 730 733,94
Total Personel Costs With Variable Salary		**€ 154 884,80**	**€ 157 982,50**	**€ 184 453,37**	**€ 188 142,44**	**€ 191 905,29**	**€ 21 927 436,86**
Other Personel Costs							
Food Allowance	€ 93,94	€ 4 133,36	€ 4 133,36	€ 5 166,70	€ 6 200,04	€ 6 200,04	€ 6 200,04
Social Security Discounts	23,75%	€ 36 785,14	€ 37 520,84	€ 43 807,68	€ 44 683,83	€ 45 577,51	€ 5 207 766,25
Workers Accident Insurance	1,00%	€ 1 548,85	€ 1 579,82	€ 1 844,53	€ 1 881,42	€ 1 919,05	€ 219 274,37
Total Personel Costs		**€ 197 352,15**	**€ 201 216,52**	**€ 235 272,28**	**€ 240 907,73**	**€ 245 601,88**	**€ 27 360 677,52**

Table 20 - Personnel costs

Source: Author

Attachment VI – Government and other public entities

GOVERNMENT AND OTHER PUBLIC ENTITIES - VAT, SOCIAL SECURITY, INCOME TAXES - CURRENT PRICES							
VALUE ADDED TAX		**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
Total Revenues (Patent)							1 086 536 697,07 €
RECEIVED VAT	**23,00%**	**- €**	**- €**	**- €**	**- €**	**- €**	**249 903 440,33 €**
Total Purchases		65 400,00 €	75 599,64 €	90 561,48 €	107 800,06 €	120 371,22 €	105 176,75 €
Investment in Assets		655 244,94 €	677 662,09 €	82 328,62 €	2 250 195,44 €	4 410 060,71 €	- €
PAYED VAT	**23,00%**	**165 748,34 €**	**173 250,20 €**	**39 764,72 €**	**542 338,97 €**	**1 041 999,34 €**	**24 190,65 €**
IVA TO RECEIVE/PAY		**- 165 748,34 €**	**- 173 250,20 €**	**- 39 764,72 €**	**- 542 338,97 €**	**- 1 041 999,34 €**	**249 879 249,67 €**
VAT TO Receive	**30**	**- 13 623,15 €**	**- 14 239,74 €**	**- 3 268,33 €**	**- 44 575,81 €**	**- 85 643,78 €**	**20 538 020,52 €**
SOCIAL SECURITY AND INCOME TAXES		**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
Wages (14 months)		154 884,80 €	157 982,50 €	184 453,37 €	188 142,44 €	191 905,29 €	21 927 436,86 €
Social Security (Company)	**23,75%**	36 785,14 €	37 520,84 €	43 807,68 €	44 683,83 €	45 577,51 €	5 207 766,25 €
Social Security (Workers)	**11,00%**	17 037,33 €	17 378,07 €	20 289,87 €	20 695,67 €	21 109,58 €	2 412 018,05 €
SOCIAL SECURITY	**30**	**4 423,76 €**	**4 512,24 €**	**5 268,29 €**	**5 373,66 €**	**5 481,13 €**	**626 283,64 €**
Personnel Income Tax (Retention)	**14,50%**	22 458,30 €	22 907,46 €	26 745,74 €	27 280,65 €	27 826,27 €	3 179 478,34 €
INCOME TAX	**30**	**1 845,89 €**	**1 882,81 €**	**2 198,28 €**	**2 242,25 €**	**2 287,09 €**	**261 326,99 €**
SOCIAL SECURITY AND INCOME TAXES		**6 269,65 €**	**6 395,04 €**	**7 466,57 €**	**7 615,90 €**	**7 768,22 €**	**887 610,63 €**

Table 21 - Government and other public entities

Source: Author

Attachment VIII – Investment

INVESTMENT - CURRENT PRICES										
					2016	2017	2018	2019	2020	2021
	Aquisition Cost	Useful Life	Dep. Tax		0	1	2	3	4	5
Accumulated Inflation Factor					**1,000**	**1,013**	**1,029**	**1,047**	**1,065**	**1,087**
FIXED TANGIBLE ASSETS										
Laboratory Equipment										
Laboratory Equipment	€ 10 000,00	7	14%		10 000,00 €	- €	- €	- €	- €	- €
Sub-total	**€ 10 000,00**				**10 000,00 €**	**- €**	**- €**	**- €**	**- €**	**- €**
Administrative Equipment										
Printer	€ 121,94	7	14%		121,94 €	- €	- €	- €	- €	- €
PC	€ 406,49	3	33%		- €	411,94 €	- €	- €	- €	- €
Furniture	€ 123,00	8	13%		123,00 €	- €	- €	- €	- €	- €
Sub-total	**€ 651,43**				**244,94 €**	**411,94 €**	**- €**	**- €**	**- €**	**- €**
FIXED TANGIBLE ASSETS	**€ 10 651,43**				**10 244,94 €**	**411,94 €**	**- €**	**- €**	**- €**	**- €**
INTAGIBLE ASSETS										
R&D Expenses										
Stage 1										
Gap analysis	€ 50 000,00	20	5%		50 000,00 €	- €	- €	- €	- €	- €
Animal proof of concept	€ 200 000,00	20	5%		200 000,00 €	- €	- €	- €	- €	- €
Pre clinical studies	€ 200 000,00	20	5%		200 000,00 €	- €	- €	- €	- €	- €
Investigation new drug	€ 150 000,00	20	5%		150 000,00 €	- €	- €	- €	- €	- €
Powder characterization	€ 45 000,00	20	5%		45 000,00 €	- €	- €	- €	- €	- €
Stage 2										
Clinical trials phase I										
Analytical methods of qualification	€ 150 000,00	20	5%		- €	- €	- €	156 990,38 €	- €	- €
Production	€ 1 000 000,00	20	5%		- €	- €	- €	1 046 602,53 €	- €	- €
Clinical studies	€ 1 000 000,00	20	5%		- €	- €	- €	1 046 602,53 €	- €	- €
Clinical trials phase II										
Stability study	€ 140 000,00	20	5%		- €	- €	- €	- €	149 132,49 €	- €
Robustness study	€ 40 000,00	20	5%		- €	- €	- €	- €	42 609,28 €	- €
Production	€ 1 900 000,00	20	5%		- €	- €	- €	- €	2 023 940,91 €	- €
Clinical studies	€ 2 000 000,00	20	5%		- €	- €	- €	- €	2 130 464,11 €	- €
EMEA	€ 60 000,00	20	5%		- €	- €	- €	- €	63 913,92 €	- €
R&D for other products	€ 80 000,00	3	33%		- €	- €	82 328,62 €	- €	- €	- €
Sub-total	**€ 7 015 000,00**				**645 000,00 €**	**- €**	**82 328,62 €**	**2 250 195,44 €**	**4 410 060,71 €**	**- €**
Industrial Property										
Patent	€ 668 000,00	20	5%		- €	676 951,20 €	- €	- €	- €	- €
Trademark	€ 295,00	20	5%		- €	298,95 €	- €	- €	- €	- €
Sub-total	**€ 668 000,00**				**- €**	**677 250,15 €**	**- €**	**- €**	**- €**	**- €**
INTANGIBLE ASSETS	**€ 7 683 000,00**				**645 000,00 €**	**677 250,15 €**	**82 328,62 €**	**2 250 195,44 €**	**4 410 060,71 €**	**- €**
TOTAL ASSETS	**€ 7 693 651,43**				**655 244,94 €**	**677 662,09 €**	**82 328,62 €**	**2 250 195,44 €**	**4 410 060,71 €**	**- €**

Table 22 - Investment

Source: Author

Attachment IX – Amortizations and depreciations

AMORTIZATIONS AND DEPRECIATIONS - CURRENT PRICES				2016	2017	2018	2019	2020	2021
	Aquisition Cost	Useful Life	Dep. Tax	0	1	2	3	4	5
FIXED TANGIBLE ASSETS									
Lab Equipment									
Lab Equipment	€ 10 000,00	7	14,28%	€ 1 428,00	€ 1 428,00	€ 1 428,00	€ 1 428,00	€ 1 428,00	€ 1 428,00
Sub-total	**€ 10 000,00**			**€ 1 428,00**	**€ 1 428,00**	**€ 1 428,00**	**€ 1 428,00**	**€ 1 428,00**	**€ 1 428,00**
Administrative Equipment									
Printer	€ 121,94	7	14,28%	€ 17,41	€ 17,41	€ 17,41	€ 17,41	€ 17,41	€ 17,41
PC	€ 406,49	3	33,33%	€ -	€ 137,30	€ 137,30	€ 137,30	€ -	€ -
Furniture	€ 123,00	8	12,50%	€ 15,38	€ 15,38	€ 15,38	€ 15,38	€ 15,38	€ 15,38
Sub-total	**€ 651,43**			**€ 32,79**	**€ 170,09**	**€ 170,09**	**€ 170,09**	**€ 32,79**	**€ 32,79**
TOTAL DEP. FIXED TANGIBLE ASSETS	**€ 10 651,43**			**€ 1 460,79**	**€ 1 598,09**	**€ 1 598,09**	**€ 1 598,09**	**€ 1 460,79**	**€ 1 460,79**
INTAGIBLE ASSETS									
R&D Expenses									
Stage 1									
Gap analysis	€ 50 000,00	20	5%	2 500,00 €	2 500,00 €	2 500,00 €	2 500,00 €	2 500,00 €	2 500,00 €
Animal proof of concept	€ 200 000,00	20	5%	10 000,00 €	10 000,00 €	10 000,00 €	10 000,00 €	10 000,00 €	10 000,00 €
Pre clinical studies	€ 200 000,00	20	5%	10 000,00 €	10 000,00 €	10 000,00 €	10 000,00 €	10 000,00 €	10 000,00 €
Investigation new drug	€ 150 000,00	20	5%	7 500,00 €	7 500,00 €	7 500,00 €	7 500,00 €	7 500,00 €	7 500,00 €
Powder characterization	€ 45 000,00	20	5%	2 250,00 €	2 250,00 €	2 250,00 €	2 250,00 €	2 250,00 €	2 250,00 €
Stage 2									
Clinical trials phase I									
Analytical methods of qualification	€ 150 000,00	20	5%	- €	- €	- €	7 849,52 €	7 849,52 €	7 849,52 €
Production	€ 1 000 000,00	20	5%	- €	- €	- €	52 330,13 €	52 330,13 €	52 330,13 €
Clinical studies	€ 1 000 000,00	20	5%	- €	- €	- €	52 330,13 €	52 330,13 €	52 330,13 €
Clinical trials phase II									
Stability study	€ 140 000,00	20	5%	- €	- €	- €	- €	7 456,62 €	7 456,62 €
Robustness study	€ 40 000,00	20	5%	- €	- €	- €	- €	2 130,46 €	2 000,00 €
Production	€ 1 900 000,00	20	5%	- €	- €	- €	- €	101 197,05 €	101 197,05 €
Clinical studies	€ 2 000 000,00	20	5%	- €	- €	- €	- €	106 523,21 €	106 523,21 €
EMEA	€ 60 000,00	20	5%	- €	- €	- €	- €	3 195,70 €	3 195,70 €
R&D for other products	€ 80 000,00	3	33%	- €	- €	27 440,13 €	27 440,13 €	27 440,13 €	- €
Sub-total	**€ 7 015 000,00**			**€ 32 250,00**	**€ 32 250,00**	**€ 59 690,13**	**€ 172 199,90**	**€ 392 702,94**	**€ 365 132,34**
Industrial Property									
Patent	€ 668 000,00	20	5%	- €	33 847,56 €	33 847,56 €	33 847,56 €	33 847,56 €	33 847,56 €
Trademark	€ 295,00	20	5%	- €	14,95 €	14,95 €	14,95 €	14,95 €	14,95 €
Sub-total	**€ 668 295,00**			**€ -**	**€ 33 862,51**	**€ 33 862,51**	**€ 33 862,51**	**€ 33 862,51**	**€ 33 862,51**
TOTAL AMORT. INTANGIBLE ASSETS	**€ 7 683 295,00**			**€ 32 250,00**	**€ 66 112,51**	**€ 93 552,64**	**€ 206 062,41**	**€ 426 565,44**	**€ 398 994,85**
TOTAL DEP. AND AMORT. ASSETS	**€ 7 693 946,43**			**€ 33 710,79**	**€ 67 710,59**	**€ 95 150,72**	**€ 207 660,49**	**€ 428 026,23**	**€ 400 455,64**

Table 23 - Amortizations and depreciations

Source: Author

Attachment X – Market assumptions

MARKET ASSUMPTIONS	
β Levered	1,02
β Debt	0,00
Equity	100,00%
Debt	0,00%
Debt/Equity	0,00%
Tax effect	81,50%
β Unlevered of the industry	1,0200
Return on risk-free assets	3,06%
Market risk premium	5,40%
β Unlevered of the industry	1,0200
Industry risk premium	5,51%
Cost of debt	8,37%
Taxes on profits	18,50%

Table 24 - Market assumptions

Source: Author