ISCTE Business School
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BUSINESS PLAN: ANTIMALARIAL SOLUTIONS

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- Spine -

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Abstract

Malaria is an infectious disease that have caused huge losses to the human being, mainly for those who live in malaria endemic regions. In one hand, public entities spend millions in methods to avoid the transmission, in the treatment of infected people or in the eradication of the disease. In the other hand, half of the human population is at risk and there is half million deaths yearly, being considered one of the most dangerous diseases.

Additionally to those who live in endemic regions, millions of travellers visit endemic regions yearly, causing an increase of the problem. As follows, the awareness around this infectious disease has been increasing, mainly due to the increase of the tourism around the world.

The incorrect use of the existing medicines has induced to increasing the parasite resistance, reducing the efficiency of those medicines. In this way, it is imperative the development and launching of new medicines that could solve this problem.

This problem was detected and both pharmaceutical companies and other entities are increasing their efforts in research and development, in order to find new antimalarial medicines that may decrease the malaria burden. However, the investment needed to the development of new medicines is excessively high, which means that not all the companies and entities are capable of performing those activities.

Considering what was said above, the main objective of this Business Plan is to analyse the economic and financial viability of the development of a new antimalarial medicine.

Keywords: Biotechnology, Pharmaceutical Industry, New Product Development and Malaria

JEL Classification: L65, M13

Resumo

A malária é uma doença infeciosa que nos últimos anos tem causado enormes prejuízos para o ser humano, principalmente para aqueles que vivem nas regiões endémicas. Por um lado, todos os anos as entidades governamentais gastam milhões de euros em meios para evitar o contágio, no tratamento dos pacientes ou na erradicação da doença. Por outro, esta doença é das mais mortíferas no mundo, estando cerca de metade da população em risco de contágio, havendo centenas de milhar de mortes por ano.

Para além das pessoas que vivem diretamente em contacto com a malária, milhões de viajantes visitam aquelas zonas anualmente, aumentando ainda mais o problema. Desta forma, a preocupação em torno desta doença tem vindo a aumentar, um pouco devido ao aumento dos fluxos de turismo mundial.

Devido ao uso indevido dos medicamentos existentes, o parasita da malária tem vindo a ganhar resistência aos mesos, sendo estes medicamentos menos eficazes. Desta forma, torna-se urgente o desenvolvimento de novos medicamentos que possam fazer face a este cenário.

Ao perceber este problema, tanto empresas farmacêuticas como outras entidades têm vindo a multiplicar esforços para que, através de investigação e desenvolvimento, apareçam novos medicamentos que atenuem as perdas provocadas pela malária. No entanto, o investimento necessário para desenvolver novos medicamentos é demasiado elevado e nem todas as entidades têm a capacidade para o fazer.

Posto isto, o principal objetivo deste Plano de Negócios é o estudo da viabilidade económica e financeira do desenvolvimento de um novo medicamento que possa combater a malária.

Palavras-Chave: Biotecnologia, Industria farmacêutica, Desenvolvimento de novos produtos e Malária

Classificação JEL: L65, M13

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Abbreviations List

- AMS – AntiMalarial Solutions
- BEP – Break-Even Point
- CEO – Chief Executive Office
- CIO – Chief Innovation Office
- EMA – European Medicines Agency
- EU – European Union
- FDA – Food and Drug Association
- IMF – International Monetary Fund
- IRR – Internal Rate of Return
- IRS – Indoor Residual Spray
- ITNs – Insecticide-Treated Nets
- LLIN – Long-Lasting Insecticidal Nets
- M&A – Mergers and Acquisitions
- NGO – Non-Governmental Organization
- NPD – New Product Development
- NPV – Net Present Value
- NWC – Net Working Capital
- ROA – Return on Assets
- ROE – Return on Equity
- ROI – Return on Investment
- R&D – Research and Development
- SCM – Supply Chain Management
- SME – Small and Medium Enterprises
- TTIP – Transatlantic Trade and Investment Partnership
- UNWTO – United Nations World Trade Organization
- USA – United States of America
- VAT – Value Added Tax
- WACC – Weighted Average Cost of Capital
- WHO – World Health Organization

Sumário Executivo

O presente Plano de Negócios da AntiMalarial Solutions surge da participação de uma equipa no acelerador de comercialização de tecnologia COHITEC, tendo como finalidade a constituição da empresa com o mesmo nome.

Este projeto tem por base o grande problema que a malária representa atualmente, tanto em países em desenvolvimento, como em países desenvolvidos. Se por um lado, nos primeiros são as populações mais pobres aquelas que sofrem mais com a malária, nos países desenvolvidos também há uma crescente preocupação com este problema. Assim sendo, com o crescimento do turismo mundial, os turistas que viajam para regiões endémicas da malária procuram mais e melhores alternativas que ajudem a prevenir a infeção. Desta forma, existe espaço para que novas tecnologias apareçam, a fim de obter medicamentos mais eficazes e que tenham efeitos secundários menos adversos.

Após uma rigorosa análise da envolvente externa, pode-se concluir que a dimensão deste mercado é bastante vasta, havendo espaço para várias empresas ocuparem o seu espaço. Além disso, e focando na malária, este é um mercado que tem vindo a crescer consistentemente nos últimos anos, devido ao crescimento do turismo a nível mundial.

Considerando a análise da competitividade da indústria, pode dizer-se que existe alguma concorrência, embora seja relativamente baixa. Assim sendo, os fatores que mais contribuem para a baixa competitividade são a elevada regulamentação e a necessidade de fazer elevados investimentos no processo de investigação e desenvolvimento. Além disso, é comum que os novos medicamentos sejam protegidos por patentes que impedem que outras empresas imitem e comercializem estes medicamentos. Estes três fatores referidos criam elevadas barreiras à entrada de novos *players* para a indústria.

Tendo em conta o que foi apresentado anteriormente, a indústria para a qual este Plano de Negócios é desenvolvido revela-se bastante atrativa. No entanto, serão necessárias algumas decisões estratégicas que permitam o desenvolvimento do *Prophyl-ACT*, fazendo-o chegar ao mercado da maneira mais eficiente. Assim sendo, devido ao elevado investimento necessário, a empresa terá que recorrer a financiadores externos, a fim de conseguir o montante necessário para prosseguir com os procedimentos exigidos. Além disso, mesmo com fontes externas de financiamento, torna-se impossível para a empresa prosseguir com as fases mais avançadas de ensaios clínicos bem como com a comercialização. Dito isto, a única alternativa plausível a seguir será o licenciamento da tecnologia a outra empresa farmacêutica logo após

a primeira fase de ensaios clínicos, sendo que a empresa terá que abrir mão das fases posteriores.

A estrutura organizacional da AMS será apenas focada nas suas atividades essenciais e naquelas que lhe conferem uma vantagem competitiva sustentável. Neste sentido, a AntiMalarial Solutions apenas terá um departamento de investigação e desenvolvimento, cuja função será todo o processo de desenvolvimento do *Prophyl-ACT*, desde o fim da prova de conceito até ao fim da primeira fase de ensaios clínicos. Adicionalmente, a empresa terá ainda atividades complementares que ficarão a cargo do Diretor Executivo e do Gestor de Marketing. Relativamente a este último, o seu papel será fulcral para a estabilidade financeira da empresa pois é o responsável pela comunicação relativa ao processo de venda da patente.

A estratégia seguida pela empresa terá por base o conhecimento dos membros da equipa de investigação acerca da malária. Neste sentido, a empresa irá adotar uma estratégia competitiva de focalização no início do processo de investigação apresentado. Consequentemente, a estratégia de crescimento da AMS fica inicialmente restringida à malária, podendo ser alargado a longo-prazo a outras doenças relativamente parecidas com esta, como são casos o Tripanossoma e a Leishmaniose.

No que diz respeito ao financiamento, será necessário angariar €1.000.000 a fim de poder começar a prova de conceito ainda em 2016. Este montante corresponderá apenas a capital próprio pois a atividade desta empresa tem nos primeiros anos uma grande necessidade de capital, o que obrigará a sucessivos aumentos de capital.

O estudo de viabilidade económica e financeira vem confirmar que o projeto em análise gera capitais suficientes para que seja considerado um bom investimento. Esta conclusão é confirmada pelo Valor Atual Líquido de €490.267, uma Taxa Interna de Rentabilidade de 16.43% e um *Payback Period* de 3 anos, 10 meses e 17 dias.

1. Introduction

This business plan aims to identify the economic and financial viability of the commercialization of a new prophylactic drug based in an innovative technology. However, since AntiMalarial Solutions will operate in the pharmaceutical industry, the technology will be out-licensed at some point in this project, it shall be calculated the potential of commercialization.

The first chapter is the literature review and it contains a theoretical framework that clarifies the reader about the main topics that may affect the success of this business plan. In this way, it includes sections about malaria, pharmaceutical industry, new product development, new product launch, and a brief review about the business models and tools used along this document.

Following this, the methodology includes the research question, the objectives to achieve with this work, the methodology and the methods used during this exercise.

After the methodology, the author presents the project by explaining the business opportunity, it introduces the technology developed, and it explains the product developed.

Following this, the author performs an external analysis, in which he elucidates the reader about the external forces, the opportunities and threats, the industry life cycle and map.

Concerning the internal analysis, it is presented the organization's structure as well a deep analysis to it, and the explanation of the strengths and weaknesses of AMS.

The competitive analysis consists on the identification of those that may affect the profits of the company. Moreover, the author identify the strategy that the company shall choose and base this strategy on the sustained competitive advantage.

Following the information collected, it will be presented a development strategy, which includes the definition of vision, mission and corporate values, as well the objectives and critical success factor. Thus, it will be disclosed the value proposition, competitive and growth strategies and the business model.

In order to communicate the value proposition to the target, the author will elaborate a marketing plan to present to the potential buyers of the patent, as well as a marketing plan to deliver the product in the market, so it will be easier to allocate costs in the financials.

Considering what was said above, there is enough information to explain the implementation of the plan. Hence, it will be presented the time-to-market, the materials and equipment needed and the implementation requisites.

Since the main objective is to understand the financial viability of AMS, the financial forecasts assume particular relevance. Therefore, it is important to explain the assumptions used to perform those forecasts. Afterwards, the author presents the forecasts of AMS until the moment of licensing the patent to other company. However, the exercise shall continue until the beginning of the sales period given that AMS needs this information during the negotiation rounds.

Finally, since this is an exercise that involves uncertainty, due to the unpredictability of some aspects, the author identifies the main risks of this project and subsequent solution that may, at least, mitigate the impact of this risks.

1.1. Objectives of the Plan

Being this master thesis a business plan, the main objective of this exercise is to evaluate the economic and financial viability of this project, considering that the company will out-license the product at some point.

The idea behind the performance of a business plan is that this document represents a useful tool in the presentation of projects to other entities. In this way, when an entrepreneur develops its business, it will write a business plan to present it to potential financial institutions or investors that could invest on his project. Following this, the analysis made must be aligned with the real world, in order to raise credibility for the project in those entities. Along these lines, the author of a business plan shall provide realistic Internal, External and Competitive Analysis in order to provide reliable information to stakeholders.

After collecting all the relevant information, the business plan will comprise the adequate strategy to adopt to face the challenges of the macro and micro environments, as well as to enjoy and take advantage of the existing opportunities.

Considering that the main objective of this business plan is related with the commercialization of the product, it means that there will be a Marketing section, where the communication strategy will be explained.

Finally, it is important to provide information about the requirements to implement the plan, the results of the plan if well implemented in the Financial Forecasts, and the Risks behind the execution of this project.

1.2. Presentation of the Project and Researchers

The project of AntiMalarial Solutions is the result of the participation of two researchers and a management student in a program promoted by COTEC Portugal. This program, COHITEC, which happened between March and July of 2015, in INDEG-IUL, allows the researchers to bring their technologies to the market, by providing knowledge and support in the implementation and commercialization of the technologies developed by the researchers. Additionally, this program ease the access of the entrepreneurs to several financial sources and give an important support in the business development phase.

The researchers that developed the technology behind the AMS Project are Liliana Mâncio-Silva and Daniel Carapau, both members of *Instituto de Medicina Molecular*. They applied to COHITEC were accepted to participate in this program, and had the help of Nuno Lopes, a master student of management in ISCTE Business School, during the program.

This technology was mainly developed by Liliana Mâncio-Silva in the past years. She is a very experienced researcher in malaria with more than ten years of experience of work in this disease. Liliana is a Post-Doc researcher in *Instituto de Medicina Molecular* and she has PhD in the Pasteur Institute in Paris.

Regarding Daniel Carapau, he joint Liliana when she started to work in the *Instituto de Medicina Molecular*, as a Post-Doc. Additionally, Daniel has a PhD in the New York University.

2. Literature Review

The literature review explains and localizes the readers in the topics approached in the business plan. Therefore, it is important to talk in this section about the pharmaceutical industry, the process of developing new medicines or, in other words, new product development in this industry, malaria, which is the disease targeted by the technology and, regarding this is a business plan, a brief explanation of the tools used in this plan.

2.1. Malaria

Malaria is a parasite disease caused by Plasmodium parasites. These parasites are transmitted to human beings through the bite of an infected *Anopheles* mosquito.

This tropical disease is a real threat to human beings given that can lead to dead when not treated on time. According to World Health Organization (WHO, 2016), 3.2 billion people are at risk of infection in 2015, and the disease caused, regarding the organization's estimates, 438 thousand deaths in 2015.

The best way to avoid any problem related with malaria is to prevent the bite of the mosquitos, even with the wide ranges of treatments of malaria. Concerning the prevention of this infectious disease, World Health Organization recommends two different methods to all people at risk of being infected. The first one is the use of Insecticide- Treated mosquito Nets (ITNs) where the most reliable are the Long-Lasting Insecticidal Nets (LLINs). The other practice important to prevent malaria is the use of Indoor Residual Spraying (IRS) with residual insecticides in order to reduce the risk of transmission (WHO Factsheet 94). Both methods are important in controlling the vector of transmission, the *Anopheles* mosquitos, but are not usually used by people that travels to malaria endemic regions.

The main problem to the fight against malaria is the resistance of the parasite to insecticides and antimalarial drugs (WHO Fact sheet number 94), being the prevention the best way to treat the problem. In this way, the prophylaxis is one of the options to people, in order to develop defences against the parasite. However, all the prophylactic medicines currently available in the market have important limitations. These drugs are Quinine, Chloroquine, Primaquine, Sulfadoxine/pyrimethamine, Mefloquine, Artemisinins and Atovaquone/proguanil, also known as Malarone, and have some problems such as safety, resistance, compliance or good manufacturing practice, unless the last one. Atovaquone/proguanil has solved all the problems of the other drugs but its price is a big limitation to people to buy it.

Given that Malaria represents a real threat for human beings and it is very difficult to fight this disease, the awareness of the society has been increasing. One important step to put this awareness in practice was the increasing number of institutions that fund research and development of new innovative ideas, as the Bill and Melinda Gates Foundation, and the increase of Non-Governmental Organizations (NGO) that develop efforts on preventing malaria transmission, resulting in the decreasing tendency of the effects of this disease. In 2013, this organization estimated 3.3 billion people in risk, while in 2015 this number was 3.2 billion. Moreover, there were 627 thousand deaths in 2013 (WHO, 2013) related with Malaria and 438 million in 2015. In the last few years, Malaria has become one of the most important diseases in terms of funding to research development, being the second most important by receiving €82.62 billion between 1997 and 2010 (Fitchett et al. 2013). According the WHO, in 2012, the global funding for malaria was €2.5 billion, which corresponds to half of what this organization considers enough per year (WHO, 2013).

The efforts performed to reduce the burden of malaria are having some effects. First of all, between 2000 and 2015 the incidence rate of the disease decreased 37%, while the death rate decreased 60%. In the case of the children, that are one of the riskier group, the death rate felt down 65%, allowing to save 5.9 million children (WHO Factsheet 94).

Being said that, there is a need of developing and launching new medicines to fight malaria. To better understand the problems behind the launching of a new prophylactic drug, it is important to understand how the pharmaceutical industry works, what underlies the development of new drugs and what is important to consider in the process of launching a new medicine.

2.2. Pharmaceutical Industry

In order to perform a deeper and more validated business plan it is crucial to have a detailed knowledge about the pharmaceutical industry and its dynamics and characteristics.

The business model that better characterizes this industry is the Blockbuster model, in which the companies try to develop blockbusters to introduce in the market with the objective of gaining high profits from the commercialization of these important drugs. However, the costs of new drugs have been increasing across the years. For example, in the 90's, the cost of developing new drugs was 1.02 billion euros, increasing to 1.58 billion euros in the early 2000s and in 2008 that figure rose to 2.047 billion euros (O'Hagan & Farkas 2009). Therefore, the companies cannot focus on all the therapeutics and diseases, because this

model will not deliver sustainable growth. Instead, they shall be “focused on the most promising areas of science and most attractive target consumers (Gilbert et al. 2003:74)”. Moreover, this author argues that the pharmaceutical companies shall find strategic partners for R&D, which will allow the companies “to manage risks and return, across both pipelines and functions (Gilbert et al. 2003).

“The traditional pharmaceutical companies cover most of the value chain of drug supply, starting from research over production to sales; the smaller and less capital-intensive biotech firms tend to focus on research and development in a clearly defined area (Holland 2004, cited by Kirchhoff & Schiereck 2011:25)”. This idea explains the dynamics of the pharmaceutical industry and, at the same time, how the increasing research and development costs shifted it. In one hand, big companies have the control of the logistics and supply chains of the industry, and their products cover a wide range of diseases and treatments, so they cannot perform a sustainable R&D to all the health problems. In other hand, the rising of venture capitalists and other types of funds helped the development of new and small companies that are focused on a specific area or disease, improving the innovation productivity. The main issue of this Small and Medium Enterprises (SMEs) is that they do not have enough capital to invest in production and it scalability, as well as the supply chain needed to commercialize the new medicines. Subsequently, the pharmaceutical start-ups are obliged to license their drugs to other bigger players in order to get the invested capital back.

Other solution that has been common in this industry is the Mergers and Acquisitions (M&A), where big companies buy and integrate in their structure the smaller one or, in the case of companies with similar size, they merge, creating a structure that is a combination of both companies. Although these operations allow companies to take advantage from synergies, there are some authors that suggest that this option is not so good given the high transaction costs. According to Pisano (1997), in cases where the transaction costs are too high, other kinds of cooperation are preferable to the firms involved. For example, small companies can license the drugs in order to avoid the expensive investments needed in the commercialization, being an advantage to the bigger company because it avoids the risks underlying the research and development phases.

The barrier to provide a new innovative drug to the market, regarding the costs, and the increasing number of medicines that are losing their patent protection, has led to the increasing presence of imitators in the industry. The main reasons to these phenomenon are

price difference to original drugs, and incentives from governments to the use of these cheaper alternatives. These firms produce drugs which patent expired, at a lower cost and practicing lower prices than the innovators. The emergence of these drugs in the market changed its dynamics by reducing the share of the companies that promote the innovation. “In 2011, Portugal, Greece and Spain reduced spending on prescription pharmaceuticals by 20%, 13% and 8% respectively (Valverde 2013: 52)”.

The emergence of these imitative companies in the industry has increased the competitiveness between firms, mainly between innovators and imitators. It is usual that the innovators make incremental changes in the drugs in order to have a longer period of patent protection. As Garavaglia et al. (2012) and Valverde (2013) observe, the overall concentration in the industry is low, but when observing a single therapeutic area, the concentration is very high.

The new product development in this industry is also a very important topic related with the present work. Therefore, it is important to enhance this process, the dynamics within it and some limitations in the model of innovation, which will be performed in the next topic.

2.3. New Product Development

According (Tidd & Bessant 2009b), innovation is not only an instrument that benefits the individual enterprise, but an activity that will favour the general society by being an important source of national economic growth. This observation highlights the importance of the constant innovation to both companies and societies. For one hand, companies that invest in new product development (NPD) are more likely to launch products that meet the customers’ needs and are more likely to answer to new challenges, gathering higher profits. In the other hand, the stakeholders of these companies will enjoy higher benefits driven from the new products.

The management of the companies are the most responsible to decide the organizations model to innovate and deliver different and better products. Nonetheless, firms shall meet the customers’ needs and wants when the new ideas are put in practice. As Christensen (1997a) defends, the customers of a company are those who control what the company can do. However, according this author, it is most common that incumbents of a specific industry tend to take advantage through sustaining innovation, whereas new entrants tend to take advantage by introducing disruptive innovative products (Christensen 2006). Yet, it can happen the case of a new entrant introducing sustaining innovation, such as the case of

Apple iPod, introduced in 2001, and keeping the same idea of the existing products (Schmidt & Druehl 2008).

The difference between sustaining and disruptive innovation lies in the impact that they have in the industry. Thus, when a technology is developed to improve the performance of an existing product, it is called sustaining innovation (Christensen 1997b). In contrast, disruptive technologies are characterized by introducing in the market new products with different value propositions and shifting the dynamics of the industry, by underperforming existing products (Christensen 1997b).

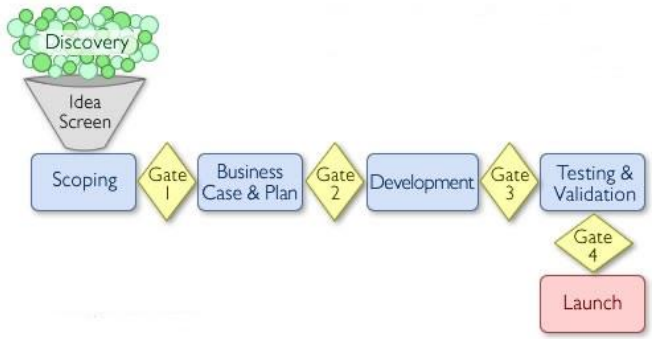
Although new product development is a beneficial activity to the enterprises it requires facing several challenges. According to (Eppinger & Ulrich 2003), these main challenges are the trade-offs between the present and future situation, dynamics given technology improvements or changes in the customer's preferences, details to ensure that everything is done the right way, time pressure and decision making without all the information, and economics regarding the increase on costs caused by the developing, producing and marketing that the new products imply.

The success of new product development (NPD) is constraint by a set of factors, as several different studies show (Tidd & Bessant 2009a). These two authors consider that there are four main success factors in NPD. The first one is the product advantage, or in other words, what the customers perceive to be better in the product when comparing with other competitors. Secondly, the homework is essential to save time and money when management assesses the market, the potential of the product and what the customers need. Therefore, market knowledge assumes special importance in new product development. Thirdly, it is relevant to understand to whom the company shall communicate and direct its efforts, which means a clear product definition. Lastly, risks are present in all projects and processes and understandings and how to avoid and mitigate, and how they will affect the new product development is crucial for the success of the project.

According to (Tidd & Bessant 2009a), new product development is a process composed by different stages, and each one is important to mitigate risks and uncertainty, from the opportunity sensing to the product launching. As it can be seen in *figure 1*, there are five different stages across the process, selecting the best ideas and eliminating the others, meaning that the process works as a funnel. At the beginning of the project there is a large number of ideas whereas at the end of the process it will remain one. Cooper & Kleinschmidt

(2001) posit that, the first stage corresponds to a preliminary investigation, in order to determine the merits and success of the ideas, selecting the best ones, allowing bad projects exclusion and avoiding higher costs. Following, the second step means a detailed investigation to each project, sensing its attractiveness through a detailed business case. This activity is performed by the management team and seeks to understand if the specificities match with the customers' needs and wants or the financial potential, for instance. After this, a prototype is developed, in stage three, in order to be tested, while the marketing and manufacturing happen at the same time. The fourth stage corresponds to testing and validation through some measures, such as customer acceptance, quality tests or understanding of production costs. Finally, the last stage is the full production and market.

Figure 1 - Cooper's NPD Stage Gate Process



Source: http://www.melodiesinmarketing.com/2008/02/25/the-stage-gate-model-of-product-development/

Regarding the pharmaceutical industry, the process of new product development is characterized by two different moments. In the first moment, the firm proceeds to the discovery of the molecule and it has the following steps: Target-to-hit, Hit-to-lead, Lead optimization, and preclinical. The second moment takes place with the development of the molecule and it is composed by the clinical trials: Phase I, Phase II, Phase III and submission to trials. This process is very expensive, mainly the phases II and III of clinical trials, being the main reason to the unsustainability of this R&D model (Paul et al. 2010).

"Pharmaceuticals are traditionally a high R&D and marketing intensive sector (Garavaglia et al. 2012:678)", this means that the pharmaceutical companies have huge investments on research and development (R&D) to discover new innovative medicines. Moreover, the requirements of the regulatory bodies have increased, which is translated in additional costs namely developing better molecules to the market.

The pattern of growth in this industry has been the development and launch of a really powerful and useful drug, also known as blockbuster, with a patent protection in order to get back the investment made in this medicine. This business model, named blockbuster model, was sustainable in the last century, but is in danger because three main reasons: the price of inputs for both discovery and development are increasing, the time value of money is getting higher regarding the time-to-market is more than 12 years, and the failure rate of new medicines is increasing (Danzon et al. 2005). Additionally, blockbuster drugs are more difficult to launch, meaning that the companies have to change their business model and rethink on how they generate sustainable growth. This problem is evidenced by Munos (2009), showing that during the last 60 years, although the increase in investments of companies in the developing new drugs, the number of drugs approved by regulators has been kept constant.

Given the problems of the R&D model in this industry, big companies need to adopt some changes to overcome this threat in the industry. An alternative option may be raising in some public institutes and universities. According to Danzon et al. (2005), the biomedical knowledge is increasing in small companies. This fact evidence an opportunity for big companies to establish partnerships with this small companies or even with universities, which are bringing new projects and new medicines. These partnerships will be effective for both parties assuming small companies can specialize on focused R&D, developing drugs for specific diseases, meanwhile the big pharmaceutical companies help in funding their partners and focus on commercialization and marketing activities, taking advantage from their well-established supply chain (Savva & Scholtes 2014).

Additionally to small and medium enterprises, the big companies have the possibility to partner with public institutes and universities. Universities are centres for creating and sharing knowledge, but they may fail in managing the use of this knowledge (Tidd & Bessant 2009b). In this way, academic institutions normally spin-out their technologies, mainly in software or biosciences sectors, in order to get commercial advantages from their intellectual knowledge. In these cases, licensing partnerships are a natural options to companies and universities (Tidd & Bessant 2009b).

Although product development is essential to the pharmaceutical industry, launching the outcome is important to get the invested money back to the firm. Thus, understanding this process may help in the comprehension of the problems underlying the present business plan.

2.4.New Product Launching

The new product development is only the beginning of the process of providing better products to the customers. As it is shown above, in the stage gate process for new product development, launching is the last phase of the overall process. However, this stage is characterized by marketing, distribution and sales activities, being the most expensive of the process. Thus, it needs a special attention, in order to better understand the impact of launching in the overall project.

In the case of new medicines, the pharmaceutical companies need to follow strict legislation in order to have their products approved. The main regulators on approving medicines are the Food and Drug Administration (FDA) and the European Medicines Association (EMA) in the United States and European Union, respectively. Although being mandatory to commercialize the drugs in both markets, the approval of these regulators is not sufficient to introduce the medicines in the market, being this only the first step. The following step is the negotiation with national entities to commercialize the drugs in the local markets. For example, EMA approves the drug after several tests and documentation confirming the results and side effects, but companies need to negotiate with national authorities, which are around 30 bodies along the European Union (Hansen and Grunow, 2015).

Time-to-market is also an important factor to take into account. The innovative medicines are commercialized under a patent protection that is conceded during the development phase. However, in this phase there is low flexibility to reduce the time, mainly in the phases II and III of clinical trials. Therefore, the market launch shall be optimized in order to avoid delays on the launching (Bauer & Fischer 2000). The profitability and the returns of the new drug depend on the time of commercialization under the patent protection since the imitators are not allowed to replicate it. Yet, after the patent expiration, the imitators easily launch generic medicines of the active compound being as efficient as the original but with much lower prices though stealing market share to the innovator.

Before the product hits the market, the company shall ensure that the target market and all the people that influence the customer to buy the medicine are aligned. “Market access materials need to reach key decision makers – the people who make policies, scan clinical research data for the emergence of new products and have responsibility for local budgets and service planning (McGrath 2010:203)”. The marketing process is, therefore, complex given

that there are a lot of influencers in decision of the final customer, which will mean high expenditures in marketing activities. In this way, “Pharmaceutical companies typically spend 1.5 to 2 times their annual R&D expenditure on marketing and promotion activities (Bauer & Fischer 2000:718)”.

Operation planning also assumes particular relevance in the sense that the company must start the production before the launching of the product. In the pharmaceutical industry this even more imperative because the “Portfolio and capacity investment decisions are all taken years before market launch”, mentioned (Hansen & Grunow 2015:130). In the case of outsourced production to contract manufacturing organizations, the time before the launching shall be higher in order to establish agreements with the manufacturers and to give them some time to plan the introduction of this new production (Boulaksil et al. 2011).

One of the toughest activities of a company in the phase of launching is to understand how the demand will act. In this way, companies shall forecast their production to meet the demand for their products. Given that, an effective supply chain management is essential for organizational competitive advantage (Schneller and Smeltzer 2006, White and Mohdzain 2009, cited by Ghatari et al. 2015). Effective supply chain management (SCM) allows companies to adjust their activities, such as production, to what the customers need in order to optimize the utilization of resources. This will allow that companies will be less exposed to external environment changes, being more prepared to give a quick and timely response to adapt to it. Thus, lean and agile supply chains are efficient ways to ensure the profitability, adaptability and viability of a company in the long run (Ghatari et al. 2015).

The topics talked above give a good contribute to understand the environment and the main challenges to perform a business plan directed to the launching of a new innovative drug. However, there are some important tools and methods related with business planning that are important to explain, so the readers of this plan understand what is behind each analysis and decision. Therefore, it is important to briefly explain the tools used to evaluate both internal and external factors of the new product and how they will impact its viability.

2.5. Business Planning and Strategy

A current practice that characterizes the raising of a new small enterprise is the elaboration of a business plan, being an important factor of credibility to important actors in the area, mainly when an entrepreneur will present their business to an investor. Its importance has been increasing along the years, being an important subject to teach in

relevant universities. However, having a good business plan is not sufficient to succeed in business, mainly for a start-up. In this way, there are several examples of companies that appeared without a business plan, such as Microsoft, and a huge number of companies that failed even with an exhaustive business plan. Moreover, there is empirical evidence that companies are more likely to spend time and resources in the beginning of the project and tend to forget this activity throughout the time, meaning that the business plan starts to be outdated (Karlsson & Honig 2009).

"A business plan may be defined as a written document that describes the current state and the presupposed future of an organization (Honig 2004:259)". In order to perform an accurate business plan, there a lot of different analysis that shall be performed, in order to collect trustful information to delineate a strategy to face future challenges for the new venture. Nevertheless, a successful strategy must ensure a consistent fit between the external environment of the company and the internal factors, like the goals, values, resources, capabilities and structural organization (Grant 2010). In this way, strategy becomes a central pillar of a business plan given that it will connect the internal factors of a company with the environment where the firm is inserted. Following this thinking, it is pertinent that in a business plan shall be clearly separated the analysis of the external environment from the internal analysis. Nonetheless, the business plan shall include a competitive analysis in order to enhance the importance of the rivalry of the market where a company is inserted. According to Grant (2010), there are four pillars that deliver a successful strategy. First of all, a company shall know its goals in the long run, in a simple and consistent way. Secondly, the management shall have a clear understanding about the competitive environment. Thirdly, the resources shall be used in the most effective and efficient way to meet the needs of the company. However, these three points are not sufficient. Thus, the forth pillar is the implementation in an effective way, otherwise the strategy implemented will not succeed.

2.5.1. External Analysis

"The essence of formulating competitive strategy is relating a company to its environment (Porter 1980:3)"

The environment plays an important role on a company's present and future, shifting the decision making of its management team. In this way, there are some useful tools that shall be used in order to carefully analyse the external environment, in order to get the most accurate prediction of what will happen in the future and what is happening right now. In this

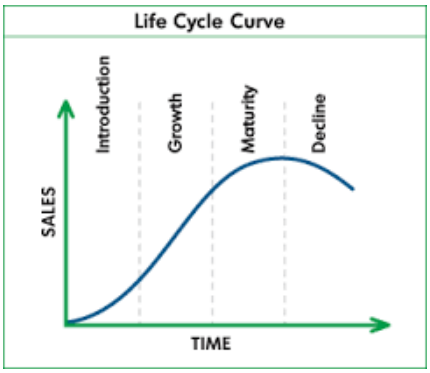
fashion, strategy definition will allow to be more competitive and ensure the survival of the company in the long run.

Performing an environment analysis by source, decision makers can understand from which source the factors that influence the enterprise come from. In this way, the **PESTEL** analysis help the understanding of the origin of the forces (Grant 2010). This analysis is divided in six main forces: political forces; economic forces; social forces; technological forces; environmental forces and legal forces.

Regarding the **political factors**, they are all the constraints derived from the political situation characterizing the market where the company operates. Thus, in this category are covered the political stability, foreign policy of the country, tax policy or the democratization process. Concerning the **economic factors**, these represent the economic situation of a country or industry. It can be included in this topic the economic growth, fiscal policy, national income, foreign debt, unemployment, and others. Thirdly, the **social factors** cover all the social situation of a country, such as life-style, education level, democracy culture, awareness of citizenship and others. The social factors characterize the way of living of the overall population of the country. Fourthly, the **technological factors** represent the easiness of an industry to access a use technologies, through investment on it. Some sub-factors of this topic are the technologic investment policies of government, new patents arising, incentives to R&D activities, adaptation to new technologies and the rate of change in technologies. The **environmental factors** of the PESTEL analysis regard with eco-friendly concerning, the impact of nature on the business and the infrastructures available. Therefore, the sub-topics are the transportation infrastructures, traffic safety, public health, urbanization level, disaster management and green issues. Finally, the **legal issues** include competition laws, judicial system, customer rights, implementation of laws and international treaties (Yüksel 2012).

One important concept that shall be enhanced is the **product life cycle**, which consists on the evolution of the sales of this product since the market introduction until its decline, passing by the growth and maturity phases. However, since companies are organizations that sell products or provide services, and an industry is composed by several companies, it can be described by a life cycle too. Consequently, the **industry life cycle** is a key tool to evaluate the macro environment of a company, being characterized by the same four phases of the products: introduction, growth, maturity and decline (Grant 2010).

Figure 2 - Industry (Product) Life Cycle



Source: http://financetrain.com/industry-lifecycle-phase-and-ma/

As *figure 2* shows, the **introduction phase** is characterized by a period of small sales and a low market penetration rate, given the unknown products of the industry. Moreover, the costs of production are high and the quality of products is low due to lack of experience with the technology. Afterwards, in the **growth stage** there is an increase on the sales and market penetration given the higher awareness of the products. To answer to the higher demand, companies increase production, transiting from premium customers to the mass market. Following this, the **maturity stage** represents the market saturation. Thus, sales are at the top, facing a declining after this, and starts the phenomenon of replacement of old customers for new customers or replacement of old products for new products. Lastly, the **decline stage** happens when other industries produce substitutes that steal customers from the industry, which impacts in a big decrease of sales (Grant 2010).

In order to conclude the literature review of the external analysis, the author must explain the analysis of opportunities and threats. However, given that those two factors are included in the SWOT analysis, which includes internal analysis variables too, opportunities and threats will be described in the last topic of the literature review.

2.5.2. Internal Analysis

As it was stated above, the main objective to build a coherent and successful strategy, is to ensure the survival of a company in the long run. However, a pillar to have a successful strategy is the linkage between the company internal characteristics with its macro environment. In this way, understanding the internal factors of a company is as important as having a deep knowledge of the outside.

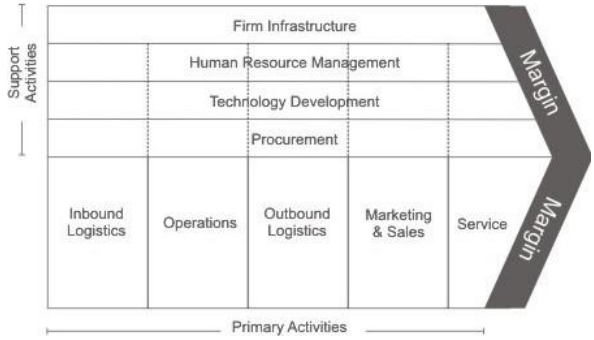
According to Grant (2010), there are four pillars that deliver a successful strategy. First of all, a company shall know its goals in the long run, in a simple and consistent way.

Secondly, the management shall have a clear understanding about the competitive environment. Thirdly, the resources shall be used in the most effective and efficient way to meet the needs of the company. However, these three points are not sufficient. Thus, the forth pillar is the implementation in an effective way, otherwise the strategy implemented will not succeed. Being said that, in this section it will be explained the tools and approaches to have a consistent knowledge of the company's resources and capabilities.

The knowledge about the internal situation is crucial to a company's management to evaluate what shall be changed to align with the external conditions. As follows, a company shall have clear and simple values and long term goals, which must be defined with the clear knowledge of the resources and capabilities of the organization, and shall be reflected on the structures and systems of the enterprise.

According Porter (1991), a company is composed by a group of economic activities that are interrelated in order to create value and deliver it to its stakeholders. Thus, the opinion of this author is that one of the sources of competitive advantage is the ability of the firm to perform the activities, according to the strategy defined by the company. In order to evaluate the source of competitive advantage and how the company creates value to its stakeholders, it is important to analyse each activity separately and define which capabilities are important to the company, so that the strategy defined is aligned with the company internal situation and external environment. To help this analysis, it will be used the **Porter's Value Chain**, a framework that combines the main activities of a company with the supporting activities of it. Following this thinking, the primary activities are defined as the core activities to a company in order to deliver products or services to customers. Therefore these activities are defined as inbound logistics, operations, outbound logistics, marketing and sales, and services. The support activities are firm infrastructure, human resources management, technology development and procurement, and they are responsible providing assets to primary activities.

Figure 3 - Porter's Value Chain



Source: https://www.mindtools.com/pages/article/newSTR_66.htm

The utilization of this framework on a business plan is useful in determining the alignment between the different activities of the company, and to understand the alignment level with the strategy defined. Moreover, given that skills and capabilities derive from performing the activities, this model is an asset on business planning by evidencing the resources of capabilities available.

As it was said above, it is not sufficient to design and delineate an adequate strategy to face the external challenges that the macro environment presents to companies, it is crucial a successful implementation of that strategy. In order to evaluate the degree of implementation of the strategy, it can be used the **McKinsey's 7 S**. This framework defines seven different factors that are crucial to the organization and divide them in hard and soft factors. Structure, System and Strategy are considered the hard factors whilst Skills, Style, Staff and Shared Values are considered the soft ones. This approach establishes a linkage between all the factors, which imply that a change in one of them will cause shifts in the other six (Waterman et al. 1980). Moreover, this framework helps managers to identify problems in strategy definition.

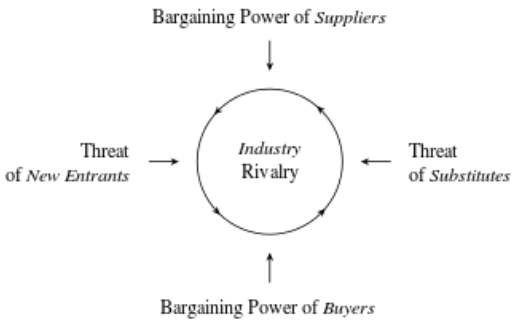
Regarding the strength and weaknesses, they will be explained later in the SWOT and TOWS Analysis Section of the literature review.

2.5.3. Competitive Analysis

Although competition is an important variable of the macro environment, its impact on the performance of a company is too high, so its analysis will be performed separately from the external analysis.

According to Porter (2008), firms compete for profits and this competition is not limited to the boundaries of the industry. As follows, company's products are not only subjected to the competition of competitors but to substitute products. Moreover, if an industry is profitable, it will bring new competitors to the competitive environment of a company. In this way, the five forces that constrain the strategy of companies are described in the **Porter's Five Forces** model. This model aggregates those forces in five main groups, as shows the *figure 4*.

Figure 4 - Porter's 5 Forces



Source: https://en.wikipedia.org/wiki/Porter%27s_five_forces_analysis

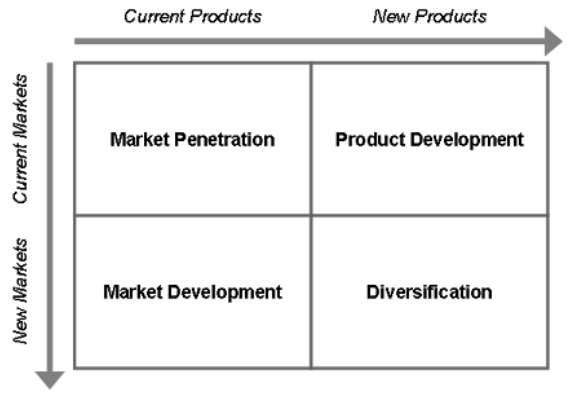
Companies develop products in order to serve their target market and obtain a compensation for those products or services. In this way, the profitability of a company will be dependent on the willingness to pay of its buyers and the elasticity of the demand for prices increases.

Bargaining power of buyers represents this relationships and the power that consumers have on the industry by being more or less sensitive to price changes. Secondly, given that the supply chain of a company is not only composed by buyers, companies shall take into account the **Bargaining power of suppliers**. The impact of price increases of raw materials and the dependence level of a company to a supplier or a group of suppliers determines the capability of a company to maintain its cost level, which is important to maintain the prices, profits and margins. Regarding the possibility of competitive companies, in a competitive and profitable industry there is always the possibility of entering new ventures, bringing new solutions of existing products. The **Threat of new entrants** represents the competition by profits within the industry. Other important products that affect the profitability of a company is the **Threat of Substitutes**, products that do not belong to the same industry but can provide identical solutions to customers. As follows, these products attract some market share, decreasing the profitability of an industry. Finally, the **Competitive Rivalry** represents the competition for profits among competitors of an industry (Porter 1979).

The strategy adopted to face the challenges of competition shall consider not only the competitive environment but the characteristics of the product and its potential market. Therefore, in order to define an adequate strategy the company shall be focused on this two factors, through the **Ansoff's Matrix**. This framework is useful for defining new strategic

directions that are important for a company to compete in different sectors and markets (Richardson & Evans 2008).

Figure 5 - Ansoff's Matrix



Source: http://www.mejoracompetitiva.es/en/2012/06/resucitando-a-igor-ansoff-tres-claves-para-decidir-como-innovar/

Regarding **market penetration**, the main objective is to increase share, which imply strong marketing efforts to attract existing customers and non-customers to buy the product at a very competitive price. However, existing products can be applied to other existing segments. In this way, **market development** means efforts to target new segments, distinguishing sustainable and genuine segments, allowing the company to have a wider number of customers.

The introduction of new and innovative products can be seen as an opportunity to create new market and industries, or to target those products to existing markets, in order to substitute the existing products. Thus, when the strategy involves the development of a new market it is called **diversification** and it is characterized by the development of a new market, delivering an innovative proposition to buyers. Though, if the new products are directed to existing markets, the strategy is named **product development** and is characterized by incremental or disruptive innovation of existing products.

Although these tools explained above give a relevant contribute on the analysis of the strategic situation of a company, their assumptions limit a deeper knowledge about the sources of sustained competitive advantage. For one hand, these models assume that the resources that deliver sustained competitive advantage are identical for all the companies in an industry (Porter 1981, Rumelt 1984, Scherer 1980 cited by Barney 1991). In the other hand, these theories assume that the resources used by companies in the implementation of their strategies are highly mobile (Barney 1986, Hirshleifer 1980 cited by Barney 1991).

Being said that, there is a lack in the analysis, which implies the adoption of other tool in order to understand the sources of sustained competitive advantage.

In order to understand the real sources of competitive advantage, **VRIO Framework** will be used. This method allows to examine the best way to use the resources and capabilities of a company according its strategy. According to this tool, the company' resources shall be **Valuable**, **Rare**, difficult to **Imitate**, and easily adopted by the **Organization**, otherwise a company will not enjoy for sustained competitive advantage (Barney 1991). In the absence of all these characteristics, a company has **competitive disadvantage**, if the resources are only valuable, the company has **competitive parity.** However, when the resources are costly to imitate, a company enjoys from **temporary competitive advantage**, but if the resources are not exploited by the organization, the enterprise will only have **unexploited competitive advantage** (Barney 1995).

Since strategy is a bridge between internal and external environment of accompany, after having a deep knowledge of the macro environment, it will be performed the analysis of the micro environment.

2.5.4. SWOT and TOWS Matrix

As it was said before, one of the main functions of strategy is to bridge the company's external environment and firm's internal structure and resources. In this way, **SWOT analysis** provides a different approach from the other tools given that analyses together both internal and external factors and forces regardless the company is in a debilitated situation or not. Yet, there is a mandatory clear distinction to do. SWOT analysis divides advantages and disadvantages between internal or external factors. In this way, the internal factors are named by **strengths**, in the case of an advantage, or **weaknesses**, if they represent a disadvantage to the company. Regarding the external environment factors, a company have **opportunities** when there are situations that bring value to the company. Opposite to this, **threats** are considered as situations that can negatively affect a company's performance (Houben et al. 1999, Dyson 2004).

Although SWOT analysis is a useful approach in sensing the strengths, weaknesses, opportunities and threats, the utility in defining a strategy is little. This strategic tool is limited in the building phase of a strategy because it assumes that a good strategy comes from a good fit between the internal resources and external events (Agarwal et al. 2012).

With the knowledge obtained from performing the SWOT analysis, it is relevant to understand the important relationships between each internal and external factors and base the strategy definition in them (Weihrich 1982). As follows, TOWS analysis establishes the linkage between the strengths and weaknesses with the opportunities and threats meanwhile defining strategies for all quadrants.

Figure 6 - TOWS Analysis

TOWS Analysis	Strengths	Weaknesses
Opportunities	S-O strategies	W-O strategies
Threats	S-T strategies	W-T strategies

Source: https://uwemarketingaudit.wordpress.com/2014/08/03/identify-swot-tows-analysis/

As the image above shows, there four types of strategies emerging from this analysis. In this way, **SO strategies** mean strategies to improve the strengths of a company maximizing the opportunities. Regarding **ST strategies**, they mean the leverage of the strengths in order to minimize the threats that come from outside. In the other side there are strategies that involve the deep exploitation of the opportunities to minimize the weaknesses of a company, named **WO Strategies**. Finally, **WT strategies** are strategies that aim to contradict weaknesses and threats through defensive strategies.

In this section of the literature review, all the most important tools of the business plan and strategy definition was explained. Therefore, the author considers that the readers are well informed to understand the logic behind the business plan and the analysis performed. Anyhow, it is paramount that readers understand the ways used to get the data and information to include in the analysis. As follows, the next chapter of the current thesis is about methodology.

3. Methodology

3.1. Research Question

The question of the investigation assumes an important role in the subsequent work developed. Therefore, the question shall represent, in one hand, the main goal to achieve in this project and, in the other hand, define the boundaries for the dissertation.

Regarding the theme chosen to this dissertation, based on the possibility of working with the investigators that developed this technology, the starting question of this dissertation is:

"Is the commercialization of a prophylactic medicine, based in a new technology and directed to travellers to endemic regions for Malaria, economically viable?"

Given that this question will guide and bound the subsequent research, it is important to ensure the clarity, pertinence and practicability of the question presented.

In what concerns with clarity, the investigation's question is done in a way that allows the readers to understand immediately what is the theme being approached during the dissertation. Therefore, the question is descriptive, by defining the main goal of the investigation and constraining the research to its objective.

The pertinence of the research question can be understood by analysing if the question is adequate to the problem under analysis. Therefore, the question stated above allow the author to understand his objective and focus in the main objective of the project, meaning that the question is adequate or pertinent.

Regarding the practicability, the question is realistic by representing a real problem to the target under analysis. Moreover, the problem is practicable because it is limited to a specific and finite number of people.

Taking into account all the arguments stated above, the author considers the research question relevant since the aim of this project is to evaluate the commercial viability of the technology under analysis. However, the industry under scrutiny bounds the investigation by requiring an exhaustive analysis to mitigate the main risks of a market characterized by high-quality research and development costs (R&D costs) and several legal restrictions.

3.2. Objectives

After defining the question of investigation, it is important to identify specific objectives underlying this business plan. These will allow the readers to follow and understand the logic behind the business plan. Therefore, the specific objectives of this project are:

1. *What are the characteristics of the travellers that go frequently to malaria endemic regions?*
2. *What is the size of this target?*
3. *Which are the main substitutes and competitors of this prophylactic medicine?*
4. *Which is the adequate strategy to implement successfully the plan?*
5. *Which is the adequate business model to be adopted?*
6. *How much money does the company needs to invest to start this business?*
7. *What are the main risks that threaten the execution of the plan? How to avoid them?*
8. *What should be an adequate exit strategy to this business? How shall the business be communicated to potential investors?*

The first two questions are a useful way to know who are the potential customers targeted, using their profiles to perform an exhaustive segmentation of the customers, and to understand the potential of the business. Moreover, knowing the clients with detail helps to adopt an adequate value proposition.

Regarding the third question, it helps the author to analyse the rivalry patent to this industry, being an important tool to define the strategy. This question represents a link to the fourth and fifth questions, in order to define the best strategy and business model to the company.

Other important remark to take with this dissertation is the investment needed to start the business. Therefore, after performing the forecasts needed, the author shall be able to understand how much money is needed to start the company, as it is asked in the seventh question.

Additionally, the author shall understand all the risks that threaten the execution and success of the project, understanding the best way to avoid them or, at least, to minimize their impact in the business.

Finally, the author shall reflect on understand if the business can be managed by itself or there should be an exit strategy. Therefore, the author must theorize about this exit strategy and how will the communication happen.

3.3. Methodology

The methodology of an academic dissertation shall be an instrument to explain to the readers the steps followed and the train of thought of the author during the development of the project. The methodology can follow three different paradigms, depending on the kind of work being performed: positivist paradigm, interpretative paradigm, or critic paradigm. In this dissertation, the author focus is work in the interpretative paradigm because he uses real information collected from databases, books or other articles and sites to justify his thinking and the strategies and decisions defined to this business plan. Moreover, since there is the interpretation of the reality in order to adapt the work to it, the paradigm used must be interpretative.

3.4. Methods

Regarding the collection of data and its interpretation, the author needs to know the size and characteristics of each segment of market, in order to decide the one that has more advantages to the success of the plan. Moreover, the author uses some tools, such as SWOT analysis or Porter's 5 Forcer, to organize his line of thought, providing the arguments and results from this analysis and basing his decisions on them. Besides the qualitative analysis, the author resorts to quantitative analysis such as the financial forecasts that help the author to justify the final remarks of this project.

The methodology used during the elaboration on this work is based on several sources of information that can be joint in some main groups: academic databases, such as B-on or EBSCO, academic books, academic papers and websites of important institutions on the area under analysis.

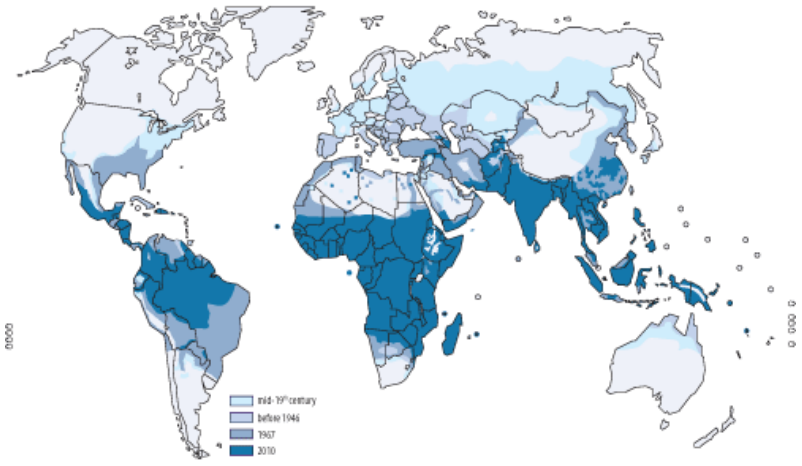
4. Presentation of the new business

The objective of the current chapter is to explain the main characteristics and goals of the new venture created from an academic *spin-off*. In this way, it will be explained how the opportunity was detected by the researches that developed the technology, the technology and the main features, and how it will be introduced in the market. Thus, the following topics will introduce in a briefly way how the idea has aroused.

4.1. Business Opportunity

Malaria is caused by a parasite named *plasmodium* and is transmitted to people through the *Anopheles* female mosquitos. This mosquitos are restricted to tropical regions, such as Sub-Saharan Africa, Central and South America, and South and Southeast Asia.

Figure 7 - Distribution of Malaria around the world



Source: http://www.rollbackmalaria.org/microsites/gmap/endemiccountries.html

In 2015, the impact of malaria on human populations was lower than in earlier years. However, there are 3.2 billion at risk of being infected meaning more or less half of the human population. Moreover, World Health Organization estimates 214 million cases in the current year and causing 438 thousand deaths.

Regarding the impact of malaria in the global wealth, the programs developed to reduce this threat have been very expensive, mainly in the endemic regions for malaria. According the World Bank, it is estimated that malaria has a negative impact of 1.3% per year on the GDP growth of the endemic countries, meaning a loss of €11 billion. Additionally, the expenditure with malaria related problems is €2.5 billion, according the Roll Back Malaria Partnership.

Regarding the prophylactic medicines available to travellers, there are some negative points that constrain the choice of the buyers. There are five medicines available that are Atovaquone/Proguanil, Mefloquine, Chloroquine, Primaquine and Doxycycline. The main struggle of using this drugs to prevent the infection is that the side effects can be very severe. In addition, these drugs are not effective in all the endemic regions.

Given that the prophylactic medicines have some cons, there is a high percentage of travellers that do not take those pills, carrying the risk of being infected. This problem is enhanced by a study of Maltezou et al. (2014) that shows the Greek situation, where only half of the population under analysis went to a pre-travel consultation and 66.8% of the travellers took chemoprophylaxis preventive medicines. Furthermore, this represents a threat to non-endemic countries because the travellers can bring the parasite to their home countries.

Being said that, it is evident a relevant business opportunity targeting the travellers to malaria endemic regions, that are estimated to be between 80 to 90 million (Petersen & Schlagenhauf 2008), distributed between Sub-Saharan Africa, Central and South Americas, and South and Southeast Asia.

4.2. Technology

AMS proposes to deliver a solution for different lacks in the market. The technology that this start-up aims to develop allows fighting different diseases caused by similar parasites. Although the business plan targets malaria as the main problem, this technology can be used in a similar way to treat Leishmania or Trypanosome.

The technology behind the product developed consists on the combination of already approved molecules for human beings. The application of this combination strongly attenuates the reproduction of the parasites in the human liver, reducing the symptoms of malaria to infected human beings. As well, the compounds used to produce these pills are known by having very low side effects, which is totally different from the competitors identified.

The main advantage of this technology remains in the fact that the compounds used will trigger the illusion to the malaria parasites that there is not enough food in the environment. Even if the environment is full of energy, the parasite will not sense it, so it will adopt a strategy that will allow it to live longer. As follows, the parasite will stop reproducing, which will help people to treat the malaria.

Being said that, the technology developed represents the introduction of a new and innovative paradigm on fighting parasite diseases. Nowadays, all the existing medicines focus on killing the parasites in the human blood. This traditional approach improves the natural selection of the parasites, which means that the resistance of medicines on the long run is more willing to happen. This is the main problem of the current medicines so that quickly becoming ineffective to treat malaria. Additionally, these existing drugs cause some dependence on users, which has impact on their health after stopping the treatment. Conversely, this technology presented does not try to kill the parasite by creating an adverse environment, which means a lower level of natural selection and, therefore, drug resistance. Currently, the problem of drug resistance reduces the five available prophylactic medicines to only two or three, regarding the geographic location of the destination of the travel. Moreover, the compounds used in *Prophyl-ACT* are known by lack of dependence, which constitutes an improvement to users.

4.3. Product or Service

AntiMalarial Solutions is proposing a new approach of fighting malaria, as it was said above. The method used to deliver this solution to the market is through a treatment of pills with a prophylactic effect. In this way, *Prophyl-ACT* will be sold as a tablet of pills enough to one week travel to endemic regions, including a period before and after the travel. This product will be available in pharmacy shops of the countries of origin of those travellers.

5. External Analysis

The external analysis will comprehend the analysis to the macro environment that underlies the commercialization of this technology. However, to perform a deep analysis, the author will use some tools such as the PESTEL analysis, the industry map, the industry life cycle and the external components of the SWOT analysis, which are the threats and opportunities.

5.1. PESTEL

This analysis is a framework that combines and describes the underlying forces of the company's activity, being important to enhance the factors that are expected to have a paramount impact on the companies. In this case, it will be described the macro environment that shifts the activity of AntiMalarial Solutions and the product launching of *Prophyl-ACT*.

5.1.1. Political Forces

Regarding the political forces, these include changes in tariffs of trade, mainly in what concerns to external policy of the countries, tax policy and fiscal policy of the countries. In this way, there are some important factors to enhance.

Being this company located in Portugal, it is relevant to briefly explain the international trade situation of this country. As an European Union (EU) Member, this country has access to a free trade zone, implying that the trade between other European Union members is free of tariffs. As follows, there is a great opportunity to export the product to other members that have strong relationship with countries endemic for malaria.

Nowadays, the EU and USA are trying to ease the trade between them. The Transatlantic Trade and Investment Partnership has been negotiated and it will offer some advantages to countries and companies on both sides of the Atlantic Ocean. In what regards to AMS, which is a Small and Medium Enterprise (SME), this partnership will facilitate the internationalization of SMEs by removing customs duties, simplifying customs procedures, reduce the costs of diverging standards or improve protection to property rights. Also, there will be a helpdesk that gives information to custom duties, taxes, regulations and customer procedures and market opportunities (TTIP Factsheet in SMEs, 2015).

Regarding the tax policy, the main changes that are predicted to happen are the taxes on corporate profits. The previous government decided, in 2013 that it was important to the economy a reduction on taxes on profits. According to this tax reform, in 2016 it is predicted

that the tax rate on profits will be between 17% or 19%. The main change that this new government wants to change is the participation exemption. Regarding the tax reform document, this exemption was of 12 years, but the new government wants to change it to 5 years to depreciate losses (PWC, 2014).

5.1.2. Economic Forces

This section of the PESTEL Analysis relies on the economic indicators that can shift the viability of the project. This may include, for instance, the inflation rate, the economy growth rate, interest rates and/or other indicators.

In the economic field, it is important to understand the current situation of the global and local economies nowadays and how it is predicted the evolution of those economies in the long run. Regarding that *Prophyl-ACT* will be sold globally, the economic indicators of the several economies are relevant because they will be a pillar to a subsequent strategy decision making process. Yet, the target market of the new drug is in the developed countries of the world, so this analysis will have a bigger focus on the EU and US economies. Moreover, given that the origin of the company is in Portugal, the economic situation of this country will be highlighted, too.

The last data available from Eurostat (Eurostatistics – Data for short-term economic analysis, 2015) shows that the global economic growth is decelerating given a slowing down of US and China economic growth. Although this deceleration, the Chinese economy is predicted to grow 6.9% in the third quarter of 2015. In top of that, the other important economy of the world, the EU economy, is already decelerated, both in the Member states of the European Union and the Euro area.

Concerning the inflation rate, it was expected around 0.0% in October 2015, recovering from negative values of September 2015. In order to overcome this situation, the European Central Bank decided to promote a program of Quantitative Easing to the European economy. The result of this program was a small increase on the inflation rates, the decrease of the interest rates to negative values. Furthermore, the exchange rates have suffered some changes, such as the euro/US dollar exchange rate that increased to 1.12 US dollars for each euro (Eurostat 2015).

Although the integration on Euro area and European Union, some countries, mainly those in the periphery, have been facing some extra difficulties. Portugal has exited from an international financial help program, provided by the International Monetary Fund, the

European Central Bank and the European Commission, some years ago and it has some economic constrains that affect the economy and life style of its society. Therefore, the increase on taxes and the decrease on family's income caused a long period of recession on the Portuguese economy. However, recently started to give positive signals and, in 2014, there was an increase of 0.9% (INE, 2015). Also, the inflation within the Portuguese economy has had values around zero, being -0.3% on 2014 (Fundação Francisco Manuel Dos Santos 2015).

5.1.3. Social Forces

The main social forces that constrain this company and product launching are related with those people who travel to malaria endemic regions, what affects their decision and why they go there.

The numbers of tourism are an important source of information to the social forces of the PESTEL analysis. According the World Tourism Organization (2015), the tourism, worldwide, increased 4.3% in 2014 and it forecasts an increase between 3% or 4% for 2015. In the long run, this organization expects 3.3% as an annual growth rate between 2010 and 2030, meaning a total of 1.8 billion arrivals in 2030.

Although the data collected from the World Tourism Organization is important, these numbers are not correspondent to the malaria endemic regions. Focusing on these locations, it is estimated that there are between 80 million and 90 million people that travel to these regions (Petersen & Schlagenhauf 2008). Anyhow, the purpose of the travel is not the same for all the people, and it could be work, recreation, religious reasons and others.. According to (Maltezou et al. 2014), the most common travel purposes to travel to endemic regions for malaria is work travels (39.7%). Consequently, it is important to have a great focus on this main group in order to understand the variables that affect their decision-making. Therefore, people that travel to malaria endemic regions with work purposes have enough purchasing power to buy prophylactic medicines. However, the side effects of these drugs and the body habituation to the drug have an important weight in the final decision (D'Acremont et al. 2007). In this case, the main reason explaining this fact is that travellers hear about people with problems caused by prophylaxis. Additionally, people who do not take prophylactic drugs is usually between 21 and 40 years old.

Finally, given that these travels have a duration of one month or less (38.1%), some people take the risk and avoid the prophylaxis.

5.1.4. Technological Forces

Technological forces may be understood in two different ways. In one hand, technological forces can be interpreted as the launching of new innovative medicines that can overcome the position of already established drugs in the market. In the other hand, the technological factors represent the already available and used technologies in the operations and marketing processes, as well as new innovative technologies that can reduce production costs and optimize the processes.

The second case described above will not be described so deeply as the first one, given that *Prophyl-ACT* will be licensed to other pharmaceutical company after the first phase of clinical trials or, maybe, after the second phase of clinical trials. In this way, the technological innovation that may affect the production is under the responsibility of the AMS client.

In what regards to the emergence of new medicines that can fight malaria, there are a lot of efforts of both private and public funds that give incentives and financial support to research and development in the area. For instance, Bill and Melinda Gates Foundation is giving million dollars per year to institutions that are developing technologies that can eradicate malaria in the world. In this way, given the lack of an effective and efficient drug in the market to decrease the negative impact of malaria in human populations, and these worldwide efforts in research and development it is highly possible the launching of a new competitor drug that will cause important risks to this project. Being said that, the company shall not stop the R&D after the out-licensing of *Prophyl-ACT* and, so, proceed to further investigation to improve the drug or develop a new one.

5.1.5. Environmental Forces

The pharmaceutical industry does not have specific environmental issues when comparing with other industries. However, the increase of an eco-friendly awareness and the need of reducing the carbon footprint may imply some extra-costs to pharmaceutical companies. Moreover, the usage of less aggressive methods to the environment may imply a different approach in the company's organization.

5.1.6. Legal Forces

The legal forces on the pharmaceutical industry are probably those that most affect the performance of companies. Given that the products that will be launched will cause some effects on human populations, there is a high burden of legislation that must be respected in order to commercialize medicines. In this way, companies must submit the new medicines to

many and costly tests in order to warrant that the drug developed is safe to be used in humans and that it will accomplish its function.

There are two important regulators that can approve drugs to be commercialized on human beings and animals. In Europe, the European Medicines Agency (EMA) is responsible for regulating the European pharmaceutical market whereas in the United States, Food and Drug Association regulates the pharmaceutical industry (FDA). In this way, any product that aims to be commercialized in the developed countries must be approved by these two market regulators.

To get the approval of these regulators, a product shall pass in a set of clinical trials (high costly and high time consuming) being one of the reasons that explain the long time to market periods on the pharmaceutical industry. Clinical trials consist on a battery of tests applied on human beings in order to study the reaction of these people to the medicine, so the safety of drug administration on humans can be understood (FDA, 2015). These clinical trials are composed by four phases:

- **Clinical Trials - Phase I** – using a population between 20 to 100 volunteers or people caring the disease, the purpose is to study the safety of the drug and the right dosage, taking several months to execute. It is estimated that only 70% of drugs move to Phase II.
- **Clinical Trials - Phase II** – this phase requires the use of several hundred people with the disease, and it can take between several months to two years of trials. This phase will challenge the efficacy and side effects of the drug and it is estimated that only 33% goes to further trials.
- **Clinical Trials - Phase III** – the third phase of clinical trials requires a population between 300 to 3000 people ill, in order to understand the efficacy and monitor the side effects of the drug. After this phase, which length can be for 1 to 4 years, only 25-30% of drugs are approved to the final phase
- **Clinical Trials - Phase IV** – this is the last phase of clinical trials and it needs several thousands of volunteers with the disease, in order to estimate its safety and efficacy.

After the clinical trials, there is a review made by the regulator in order to evaluate if the product can or cannot go to the market.

Although there is more legislation to regulate the pharmaceutical industry, what was described above is the big deal in the industry and one of the reasons to the unsustainability of

the Blockbuster Business Model. For one hand, clinical trials are very expensive, which implies high investment needs, mainly in new comers to the industry. On the other hand, clinical trials represent a selection process given that only a small number of drugs developed are approved after clinical trials, causing high R&D costs.

5.2. Industry Map

The industry map is a tool used to describe the complete supply chain of a company and what are the most important relationships within it to a company. In this way, it is important, throughout this process, to identify the manufacturers of raw materials, the suppliers, distributors, wholesalers and customers. In other words, industry mapping helps to identify the upstream and downstream relationships that a company shall keep. The industry map that represents the pharmaceutical industry can be described as follows:

Figure 8 - Pharmaceutical Industry Map

Source: Author

Starting from the beginning of the process, the producers are composed by those companies that extract the raw materials to produce *Prophyl-ACT*. As it was mentioned above, this drug results from the combination of different already approved compounds, so their producers are well known.

Regarding the manufacturers, these represent the companies that may combine the different compounds into a single product. These companies provide support to pharmaceutical companies in manufacturing and in the packaging processes of the medicines. Companies like Parchem (USA), Bactolac Pharmaceutical Inc, AIDP Inc, AIBMR Life Sciences (USA) and Nexira (France) are within this group.

The pharmaceutical companies are the central group in the industry map in this business plan. AMS is present in this group, which is composed by different types of companies. In one hand, there are companies that focus on R&D and aim to out-license their products to the giants of the pharmaceutical industry or to be bought and integrated on their structure. This is the case of AMS, whose business model focus on providing innovative solutions to the industry. In the other hand, the big pharmaceutical companies are characterized by investing on the development of blockbusters in order to have revenues of billions in the market. These companies have an important role because they have power to

merge with other companies or acquire smaller ones to commercialize their products. In this business plan, these big companies can be understood as possible clients of AMS given that they may buy the industrial property of *Prophyl-ACT*. In this group, there are companies such as GSK, Pfizer, Novartis, Roche or Merk.

In order to have lower distribution costs, a company in this industry shall utilize synergies with well-established distributors and wholesalers, lowering the operation costs and fixed assets. In this way, the entrance in each country's market shall be made through a partnership with the most competitive distributors, which deliver medicines to hospitals and pharmacy shops.

Final retailers are represented by the pharmacy shops where the medicines will be available for sale, where the final customers, those 80 million people can buy *Prophyl-ACT* before going to malaria endemic regions.

5.3. Industry Life Cycle

The industry life cycle is an important approach to understand the attractiveness of the market where a company operates or where new companies want to enter. Therefore, it is important to identify the phase of the pharmaceutical industry is in order to understand if it is worth to enter this industry and which could be the best strategy to do so.

As it was described in chapter 2, the growth stage of the industry life cycle is characterized by fast market penetration, standardization of dominant technologies, quality improvements through the emergence of a dominant design, mass production and competition for distribution, exports from developed countries to the rest of the world, several transactions through mergers and acquisitions and several companies entering the industry (Grant 2010).

Taking into account what was described above as characteristics of an industry in the growth stage, the pharmaceutical industry can be consider as an industry in growth. In this way, a lot of different medicines are launched every year, which implies a longer duration of this growth stage. In this specific case, the patent protection required to commercialize an innovative medicine extends the length for each product by conceding a quasi-monopolistic position to the inventor. Moreover, the concentration of knowledge in universities and public entities contribute to the appearance of biotech based start-ups, aiming to enter the market. However, given the big investments that are vital to launch the product, these start-ups tend to be bought by pharmaceutical giant companies, through acquisitions processes. Furthermore, it is common in the industry the existence of mergers between big companies, as it happened in

the case of Pfizer and Allergan, which signed a merger deal that is considered the biggest in the history (Fortune, 2015).

Considering what was said above, the company might be optimistic with the development of this drug due to its characteristics. In this way, it is expectable that there will be one, or maybe more, companies interested in commercializing this drug, given that the market is growing and the drug has important advantages in core characteristics to its competitors, such as the low severe effects and the absence of habituation of the human body. Moreover, the patent provides a privileged position in the commercialization, which can attract a big number of customers to this product. Concluding, given the phase of the industry life cycle, it is highly possible that more than one company will be interested on acquiring the patent of *Prophyl-ACT*.

5.4. Opportunities and Threats

Opportunities and threats are the external factors of the SWOT analysis that can constrain both performance of a company and the decision making whilst the strategy definition. In a brief explanation, opportunities can be described as external events that may create value to a company if it invest to enjoy this event. In contrast, threats are external events that can threaten the performance of a company and shall be avoided. (Appendix, *Table 26* – SWOT Analysis)

Opportunities

- Market size;
- Market growth, due the sustainable increase on the numbers of tourism;
- Existing and well-established distribution channels;
- High number of travellers that do not take prophylactic medicines to avoid malaria;
- Important lack on prophylactic solutions to avoid malaria;
- Possibility to out-license the drug to well-established pharmaceutical companies;
- Possibility of using the technology in different applications;
- Adverse effects of the existing prophylactic medicines

Threats

- Low price of direct competition
- Worldwide effort to develop alternative products to treat malaria;
- High possibility of new entrants with better solutions.

6. Internal Analysis

With the internal analysis, the author aims to understand the internal situation of the underlying technology/project, in order to define a coherent strategy that will allow the fit to the most important objectives defined.

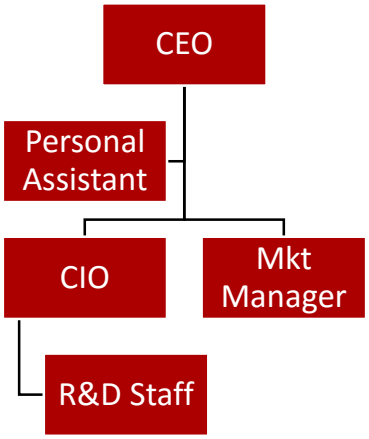
6.1. Organization's Structure

AntiMalarial Solutions is a pharmaceutical company created to develop innovative technologies focused on the fight against malaria. So that, it is essential to make a clear division between the period before the market launch of its product, the *Prophyl-ACT*, and the product launch and subsequent commercialization. Being said that, AMS will only develop the medicines until the end of Phase I of Clinical Trials, proceeding to the sale of the patent of the drugs developed afterwards.

Although the company will only held responsibility on developing the medicine, it is important to continue the exercise and present all the variables that may affect the commercial viability of *Prophyl-ACT*. Thus, after the presentation of AMS's structure, it will be presented a suggestion of a structure of the company as if the company would go to the market, with the correspondent cost structure, investments, variables and the potential of sales. With this, the author aims to collect enough information to present to a possible buyer during a negotiation round to proceed to the transaction of the industrial property.

Considering what was said above, the company will have a simple structure to operate. Given that the company aims to develop innovative solutions to reduce the malaria burden, the core activity of the company will be the research and development. Thus, the organizational structure can be represented in the following chart:

Figure 9 - AMS Organizational Structure



Source: Author

At this stage AMS team will be composed by the CEO, a CIO responsible by R&D Staff, a Personal Assistant to support the CEO and a Marketing Manager. Their own responsibilities are different, concerning their place in the structure and will be described below.

Chief Executive Office

The CEO has the responsibility of managing the company as well as for the decision-making process. In this way, the CEO shall delineate the strategy that the company shall follow and ensure that all departments are coordinated in order to accomplish with this strategy. In this way, he will have functions of managing and monitoring the daily activities in order to ensure that the objectives are achieved.

He will also play an important role on R&D strategy definition, as well as the communication strategy, giving some support to both CIO and Marketing Manager, respectively. In the case of R&D, the role of the CEO is essential to delineate the pipeline of investigation. In addition, the CEO is responsible for the process of human resources management.

Concerning with the company external relations, the CEO shall be present on international events related with drug development and malaria, in order to create a strong and valuable network to the company, as well as giving visibility to AMS. These two functions will be crucial in the company's accomplishment of its goals.

Personal Assistant

This person will give support to the CEO, mainly in managing the CEO agenda, by scheduling his meetings and participation on all the events. Moreover, this staff must provide support on preparing documents to the CEO.

Chief Innovation Office

The CIO of the company will be a Senior Ph.D Researcher, with expertise and experience on the R&D, mainly in the field of malaria. His main task will be the management of the R&D process and the coordination of his team. Moreover, the CIO will discuss the strategy of his department with the CEO, as well as the strategy to define the pipeline of investigation that the company shall follow. Finally, when there are needs of human resources, the CIO will have the final decision on recruiting staff to his department.

R&D Staff

The R&D team will be composed by a Clinical Trials Specialist and several Lab Technicians with some experience in this area.

Concerning the Clinical Trials Specialist, he will be responsible for all the process of the Phase I of Clinical Trials. Their main functions will be the preparation of the product to go these trials, to manage this process and to be coordinated with the other R&D members in the lab. This staff must report to the CIO. He will also be responsible for all the matters regarding approvals and product registration processes.

In the other hand, the Lab Technicians will be responsible for the daily work on the lab, mainly by performing the scientific experiences in the development phase, reporting all the information to the CIO.

Marketing Manager

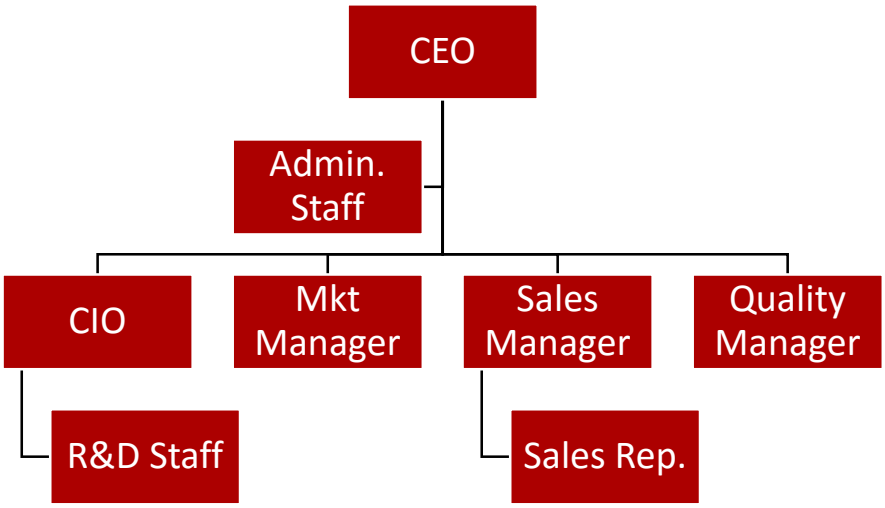
The Marketing Manager will be responsible for developing an adequate strategy for two different audiences. In one hand, the marketing manager shall develop a consistent communication strategy to the financial investors of the company, in order to raise enough funds to pursue with this project. In the other hand, he shall define the communication strategy to attract possible buyers to the patent protection.

Concerning the potential buyers, this staff must travel, when needed, with the CEO in order to publicize the company to other important external entities. In this way, he shall not only report to the CEO, but align his agenda with him.

Now, that the company's structure is defined, the exercise shall continue, supposing the company goes to the market and commercialize itself the product. It is important to enhance that this is only made in order to have an accurate idea of the commercialization value of *Prophyl-ACT*.

Considering what was said above, the following company's structure would exist if AMS would go to the market, instead of licensing the product:

Figure 10 - Organizational Structure of Commercialization



Source: Author

In this structure, the CEO, CIO, Administrative Staff, and R&D Staff have more or less the same responsibilities of the real structure of the company. The Marketing Manager will have additional tasks mainly in the definition of the marketing mix.

Regarding the other members in this structure, the Sales Manager will be responsible for managing the sales force as well as give support to clients of the company. The sales representatives will sell the product to well-established distributors in each country and to communicate intensively with tropical diseases doctors to promote the product. Concerning the Procurement Staff, it will be responsible for acquiring the best possible raw materials at the lowest price possible and deliver it to the manufacturers. After the manufacture, the Quality Control Manager will responsible for evaluating the final product in order to guarantee the high quality of *Prophyl-ACT*.

6.2. Porter's Value Chain

Porter's value chain allows decision makers to understand if company's main activities are well divided among the right departments so that answering the question: how does the company creates value for its customers.

As it was said before, AMS is a company focused on developing new solutions to reduce the burden of malaria worldwide. Given that, its focus on R&D will allow developing more innovative solutions based on the expertise of its staff. However, in order to provide a deeper evaluation to external entities, it is important to identify the source of value creation of the company and to explain the interactions between the different activities of the company.

The support activities of AMS will be performed mainly by the CEO and the Personal Assistant and the CIO. Thus, the CEO will manage the human resources of the company. Regarding the procurement and technology development, this will be responsibility of the CIO, in order to bring to the company the most sophisticated technology, and to purchase the materials needed to the R&D staff.

The primary activities will be relegated to the R&D department that will work on developing innovative technologies in order to the company sell its patent to other companies. In this selling process, the marketing manager will have an important role in defining the adequate communication strategy to attract the higher number of companies interested in acquiring the patents of the company.

6.3. McKinsey's 7S Framework

McKinsey 7s will provide, at this point, an important summary about the internal alignment of the company, so that answering to the external challenges that AMS faces.

Structure

AMS has a simple structure focused in its core activity, and with other supporting staff to accomplish other activities in order to have an efficient method of work.

Strategy

AMS' strategy is based on the main source of its competitive advantage which is the technical competencies of its staff, allowing to develop innovative technologies.

Systems

The organization of the daily work allows the company to divide clearly the daily tasks according to the expertise of its staff.

Skills

The company aims to recruit people not only with well-developed hard skills but with soft skills like teamwork, cooperation, leadership and resilience..

Style

The company's leaders shall be practice a leadership focused on people, in order to improve the motivation of work, recognizing and giving incentives based on people's work merit.

Staff

The company shall recruit people with strong experience in the area, mainly in pharmacology and malaria, allowing efficiency in the R&D process.

Shared Values

The company and its workforce shall have high determination to achieve great goals, efficiency, dedication and innovative thinking to develop the company.

6.4. Strengths and Weaknesses

Regarding the internal perspective of SWOT Analysis, the variables can be organized as strengths, which correspond to the determinant capabilities and resources to achieve success, and weaknesses, characteristics of a company that may cause a negative impact in specific situations. (Appendix, *Table 26* – SWOT Analysis)

Strengths

- Easy Communication of the solution delivered;
- Product performance;
- Team's knowledge about the area of malaria;
- Use of already approved compounds;
- Simplicity of the organization's structure;
- Tasks well defined within the company;

Weaknesses

- Legal procedures require high investments;
- Lack of network to establish the needed agreements and partnerships;
- Lack of knowledge of the total costs of the business;
- High funding needs due to expensive R&D;

7. Competitive Analysis

Although competitive analysis can be included on the external analysis, it assumes a relevant role on strategy definition and performance of a company that justifies this separation. The focus of the competitive analysis is the market and the competition for profits that the firms perform on a daily basis. In this analysis, the author uses Porter's 5 Forces, Ansoff's Matrix, TOWS Analysis and the VRIO Framework to get the most detailed knowledge possible from the market environment.

Considering the business model adopted by AMS, the competitive analysis is performed to comprehend the competition of AMS, as well as the commercial viability of *Prophyl-ACT* in the market. Therefore, it is important to provide a deep analysis on the challenges that this commercialization will face in order to present it during the negotiation of licensing the patent of the product to other pharmaceutical company.

7.1. Porter's 5 Forces

This strategy model consists on performing a detailed analysis about the main five forces that shape the competitive environment: bargaining power of buyers, bargaining power of suppliers, threat of substitutes, threat of new entrants, threat of substitutes and competitive rivalry within the environment. In this way, it is possible to evaluate the potential profitability of the industry, which is a decisive factor on the construction of this business plan. Therefore, this analysis will be made through a weighted average of the different criteria used to quantify the different forces (Appendix, *Table 27* – Porter's 5 Forces).

Bargaining Power of Buyers

The bargaining power of buyers represents the power that the buyers have to stop consuming a company's product. In order to evaluate this power within the pharmaceutical industry, and focusing in the disease of malaria, there are some important considerations to do.

First of all, the market size for this specific therapeutics is relatively high. According to Petersen & Schlagenhauf (2008), there were between 80 million to 90 million travellers, in 2008, to malaria endemic regions. Secondly, given that there are some alternatives in the market and there is the possibility of stop taking the drugs, the client's cost to change the medicine are low, increasing the bargaining power of buyers. Other measure that shifts the bargaining power of the buyers is the severity of the side effects that the consumer has after

taking the medicines, preferring drugs with lower adverse effects to health. Additionally, it is important to enhance the information availability, in the way that with the pre-travel consultation, travellers are informed about the most adequate antimalarial to buy. After the pre-travel consultation, people will make a decision about taking or not prophylaxis to avoid the infection. As follows, since the customer takes the final decision, taking into account the opinion of the doctor, the bargaining power of buyer is high (3.71). This situation happens because this therapeutic is a prophylaxis to avoid the infection instead of a cure to this infection and because there is an important percentage of the travellers that is willing to risk and travel without prophylaxis.

Bargaining Power of Suppliers

To evaluate the bargaining power of suppliers, it is important to take into account three variables: the size of AMS in the case of commercializing by itself the product, the number of suppliers available in the market, and the probability of these suppliers combine the prices in order to maximize their profit.

In this way, given that the company is small, the suppliers' profit does not depend on it, so that they are willing to start to combine prices in order to maximize their profit. Moreover, the number of suppliers available is moderate, which does not benefit the company. In this way, the dependence of AMS to its suppliers is very high so their bargaining power is very high, with a global force of 4.33.

Threat of Substitutes

The existence of substitute products is other important fact to account on this analysis. The substitutes already used in the market are methods to avoid the mosquito biting. In this way, the efficacy of these products is limited and it is not the best way to avoid malaria infection. Moreover, the number of substitutes that exist in the market is small, which makes the threat of substitutes low, with a global force of 1.5.

Threat of New Entrants

New entrants are other force that shall be deeply analysed. Given the increase on the awareness of the problem, there are more efforts to develop products to reduce the burden of malaria. In this way, the incentives to R&D are high and there is an increasing number of venture capitalists that are interested in biotechnology start-ups researching this topic.

Yet, given the implications of new medicines in human population, this is a sector that is highly regulated by the government institutions. Thus, the legal requirements needed to fulfil in order to develop the new drugs are a high barrier to new entrants. Moreover, these legal requirements cause high needs of capital to spend in R&D or legal issues, which constitutes another important entry barrier. Additionally, the time to market period is more or less 10 to 12 years, being half of the patent period. However, the increasing investment on R&D in the area will bring to the market at least other competitor that may trouble the commercialization of *Prophyl-ACT*. Therefore, the threat of a new entrant in the market is moderately high, with a global force of 2.67 out of 5.

Competitive Rivalry

The last force that shifts the competitive environment of a company is the competition level within the industry. In the case of *Prophyl-ACT*, the most important competitors are Atovaquone/proguanil, also known as Malarone (brand name), and Mefloquine.

Side effects are an important factor when the customers decide which prophylactic medicine they will use. In general, excluding Atovaquone/Proguanil, all the existing medicines have severe side effects. In this way, Malarone has enjoyed a privileged position in the market. Additionally, the parasite resistance to all these products is increasing, so they are losing efficacy. Moreover, the price is other variable that influences the buying decision of the travellers. Regarding the price, the most expensive is Malarone, but its patent protection has expired recently. Following this, the competitive rivalry has a moderate global force of 2.5, mainly due to the low price of the competitors whose patent expired.

Considering the analysis performed to each force of the model, there is evidence to say that the industry being studied has a good potential to generate profits to the company given that, in general, all these forces have a moderate or low impact on the company's performance.

7.2. Ansoff's Matrix

The Ansoff's Matrix helps the decision makers to understand what the adequate strategy is relying on the competitive advantage of the company, by analysing the inherent characteristics of the product and the needs of the target customers. In this way, there are four different strategies to adopt: market penetration, market development, product development or diversification, as the Figure 11 shows.

Table 1 - Ansoff's Matrix

		Product	
		Existing	New
Client's Need	Existing	Market Penetration	Product Development
	New	Market Development	Diversification

Source: Adapted from I. Ansoff (1965) Corporate Strategy, Penguin, Harmondsworth (1968) toward a strategy of a theory of the firm, McGraw-Hill, New York

Considering the characteristics of the market and target clients, it is recognizable that there is an existing market need that is not satisfied by the existing antimalarial prophylactic medicines. In this way, customers demand drugs with less severe side effects and with lower parasite resistance.

In the other perspective, the product that AMS presents to the market is innovative, by combining compounds that are already approved to human consumption and that have prophylactic characteristics. Moreover, these products are known to have very low side effects and low rate of habituation by the human body, and are easily available in the market.

In order to capture the value created by the commercialization of *Prophyl-ACT*, the company that will commercialize the drug shall proceed to a premium price strategy, so that seizing extra benefits this medicine brings compared with the other drugs, like the absence of adverse effects. In this way, Malarone is currently the most expensive product in the market, with a price of €32.17 in Portugal. Therefore, the price to end user of *Prophyl-ACT* shall be higher than this.

7.3. TOWS Analysis

Although the SWOT Analysis gives an important analysis of the environment that constraints the activity and performance of a company, it is, in a certain way, limited because it does not indicates how to face the cons using the strongest points of both internal and external environments of the company. Being said that, TOWS Analysis provides the answers that shall be answered to those challenges, giving insightful ideas on how to face weaknesses and threats by using strengths and opportunities. In this way, SO provides an idea of how to use strengths to take advantage from opportunities, ST indicates the way to use strengths to minimize the threats, WO concerns with the strategies to minimize weaknesses by enjoying opportunities, and WT regards with strategies to minimize weaknesses and avoid threats. (Appendix, *Table 28* – TOWS Analysis)

SO

- Communicate the product to attract travellers that buy other prophylactics;
- Communicate the product to travellers that do not buy the prophylactic;
- Use the team's knowledge to apply to research and development funds and get financial assets to accomplish the plan;
- Use the team's knowledge to develop other solutions
- Provide a simple communication to attract possible buyers to the patent.

ST

- Development of a high performance product to facilitate the approvals on legal procedures and clinical trials;
- Maintain a simple structure to better cope with the uncertainty and keep the costs under control;
- Use of this technology in other ways, in the case of not getting the approval on clinical trials;
- Out-license, as a way to avoid the huge investments on further clinical trials and commercialization;
- Product performance and easy communication to raise funds to Clinical Trials Phase I/II-A

WO

- Use the market size and market growth as an argument to increase the selling price of the patent;
- Explore the lack of solutions to develop an important pipeline of investigation, reducing the dependence of a single product;

WT

- Reduce the time to market and avoid being overpassed by new competitors in the market;
- Getting approval on clinical trials in order to avoid more investments in R&D and legal procedures;
- Seize the worldwide effort to develop new antimalarial medicines to attract investment and funding to reduce the expensive R&D activities.

7.4. VRIO Framework

In a competitive environment, a company needs to have some specific resources or capability that makes it different from the other competitors and attracts customers to the company. In this way, VRIO Framework allows understanding the sources of competitive advantage and how sustainable is that advantage. The following chart explains how VRIO works:

In order to perform the analysis following this framework, first, it is relevant to identify the resource or capability of AntiMalarial Solutions that is willing to provide competitive advantage to the start-up. As follows, the company defines itself as being created to develop innovative solutions to the market that can help fighting the malaria infection. *Prophyl-ACT* results from this orientation of the company.

Considering what was said above, AMS has to identify the resources considered the sources of competitive advantage. So, the core resources of the company are the highly experienced human resources and their knowledge and technical competencies. These resources have a crucial role on pursuing with the research and development of *Prophyl-ACT* until the end of the first phase of clinical trials. After that, the company will base its activity on these resources to start the R&D of new products, developing a strong pipeline of investigation for the future.

Applying the VRIO Framework on these resources, the company may have a sustainable competitive advantage. These resources are valuable given that they are responsible for developing new medicines ensuring the company's sustainability. AMS is able to capture the value of these resources on the future negotiations of the patents. Moreover, these resources are rare due to the work experience acquired. As follows, the researchers of AMS are Ph.D Researchers with more than ten years of experience on malaria, with several publications and presences in international events about malaria. Considering this, it is difficult to a competitor to imitate this, due the scarcity of resources like that in the market. Finally, the company is organized to capture value from these resources due to the commercialization of the patents of the products developed. Therefore, AMS has a sustainable competitive advantage that can use in the long run in order to achieve its objectives and overcome the challenges of the external environment.

8. Development Strategy

The development of AntiMalarial Solution's Strategy will be designed taking into account the characteristics of the product that will be proposed to the market as well as the characteristics of the targeted market and its competition. In this way, Porter's Generic Strategies is a useful framework since it analysis which is the most adequate strategy to follow.

Table 2 - Porter's Generic Strategies

Big Market	Cost Leadership	**Diferentiation**
Small Market	Focus Strategy	

Source: Adapted from Competitive Advantage: Creating and Sustaining Superior Performance; Michael Porter (1980)

Being said that, the adequate strategy to follow according the product under development is a differentiation strategy given that the *Prophyl-ACT* has paramount characteristics that other competitors do not have and there is a wide ineffectively fulfilled market to serve.

Following this, it will be described the internal values and assets that can lead the company to achieve success in the long run.

8.1. Vision, Mission and Corporate Values

Vision

The Vision of AntiMalarial Solutions is to be a world reference on fighting and minimizing the burden of malaria.

Mission

Through focused research and development in fighting malaria disease, AMS intends to provide innovative therapies to the market, offering better solutions to minimize the effects and costs associated with malaria.

Corporate Values

AMS is a company created to develop innovative medicines focused on a specific therapeutic. Along these line, the values that will guide the activities of AntiMalarial Solutions will be:

- Social Responsibility – by promoting events and campaigns to help people that are affected by malaria;
- Innovation – developing new products imply thinking out of the box;
- Sophistication – using the most adequate and ultimate technology and methods to develop better products;
- Proximity – establishing close relationships with all the stakeholders, in order to share the value created with all of them in a fair way;
- Equality – similarly with proximity, AMS aims to share the value created with their shareholders and people struggled with the burden of malaria.

8.2. Critical Success Factors

Given that AMS follows a differentiation strategy, its focus will be on the continuous improvements of the products and respective characteristics as well as developing new products. Therefore, the core activities of this start-up will be R&D activities. In this way, the Critical Success Factors to accomplish this plan will be mainly focused on R&D and they will be the following:

- Product developed achieves the expected performance;
- Approval on Clinical Trials Phase I;
- Start negotiations with other pharmaceutical companies;
- Start R&D to other therapies;
- Sell the industrial property to other pharmaceutical company.

8.3. Value Proposition

As a R&D company, AMS aims to create value in the first phase of a medicine's life. Thus AMS creates value to the society through intensive activities of R&D in order to develop innovative technologies to solve health issues related with malaria. Given that AMS is a company focused on technology development, the company will sell the rights of commercialization to other companies, in order to get the investment back.

The value creation of AMS can be observed in *Prophyl-ACT*, which is a therapeutic with unique characteristics. Therefore, this drug strongly attenuates the infection and reduces the disease risks to human life. By not killing the parasite, this drug does not activate mechanisms of natural selection, which implies a lower probability of parasite resistance in the long-run.. Comparing with other prophylactic medicines, this drug has very low side

effects to patients, which represents the most important differentiation factor and it is a good example about what AMS wants to deliver to the society.

8.4. SMART Objectives

In order to follow a consistent path and measure the accomplishment of the plan, the project shall have objectives to achieve. Yet, these objectives shall be SMART, or in other words, specific, measurable, achievable, realistic and with a specific period of time to accomplish it. Being said that, the SMART Objectives of AntiMalarial Solution's business plan are:

- Raise investment of 1.000.000€ at the end of 2016 to start the Proof of Concept;
- Recruit, in 2016, the R&D Team, the Personal Assistant;
- Raise 400.000€ to start the Clinical Trials Phase I/II-A.
- Finish the Proof of Concept in 2017 and start the Clinical Trials Phase I/II-A
- New round of investment to face the financial needs in a value of 2.000.000€; in 2017;
- Finish the Clinical Trials Phase I/II-A in 2019 and start to prepare the licensing process;
- Out-license the product to an established pharmaceutical company at the end of 2019, receiving 6.000.000€ for the patent.

Although one of the SMART objectives is to out-license the product to other company in 2019, it is important to continue the exercise of estimating the commercialization value of *Prophy-ACT*, in order to present the value that the possible buyer will earn in the commercialization of the drug and what is the net present value of it.

8.5. Resources, Capabilities and Strategic Competencies

Although AMS is in the beginning of its life, the company already has a sustainable competitive advantage in the market. As follows, resources, capabilities and strategic competencies are a pillar to the strategy of the company in the long run. The company shall base its activities on that in order to overcome future challenges, such as the end of the patent protection. Yet, in the beginning, the company shall assent its activities on the product.

Competitive Advantage based on Resources:

- Innovative drug protected by a patent;
- Technology as a mean to improve R&D;
- Highly qualified human resources, mainly in R&D.

Competitive Advantage based on Capabilities:

- Expertise on R&D focused on developing new drugs focused on Malaria;
- Adaptive structure of the company;
- Advantage from using innovative technology in R&D and efficient methods;
- Efficient structure that allows low fixed costs.

Competitive Advantage based on Strategic Competencies

- Strategic thinking to establish the right path to a sustained growth;
- HR Management focused on the employee, in order to optimize the workforce efforts;
- Equality and fairness to give the right incentives to those who deserve it.

8.6. Competitive Strategy

The space of AMS in the marketplace is different from a typical pharmaceutical company. Whereas those companies invest billion dollars on their activities from R&D to marketing and market activities, AMS will only focus on the beginning of the process, being specialized on R&D. This allows the company to be focused on the most indicated areas according to its core capabilities, avoiding an expensive and ineffective supply chain to commercialize the drug.

Being said that, the competitive strategy of the company will be based on the continuous development of new patented drugs in order to make the company profitable. Therefore, the company shall build an important network and visibility in the community around the area of malaria, in order to increase the awareness of the big companies on its patented drugs.

8.7. Growth Strategy

The growth strategy of AMS shall be based on the deep knowledge and experience of its teams and the characteristics of the medicines and the diseases. Being said that, the drug will invest on finding other types of solutions of antimalarial drugs, in order to answer to other needs of the international community. In this way, an important market to target after the travellers are those people who live in a daily contact with the Malaria, mainly directed to pregnant women and children because these two groups cannot take antimalarial drugs.

Moreover, diseases like Leishmania and Trypanosomes since they have a similar mode of action as malaria they also constitute a possible strategy to follow.

8.8. Business Model

AntiMalarial Solutions have a common business model to a pharmaceutical start-up. In this way, AMS is a company created to develop antimalarial drugs and deliver it to the customers through licensing them to other companies that may commercialize those drugs.

The company is organized to create value on the beginning of a drug's life. In this way, the company's structure is organized to on R&D activities.

Given that the company will license patented drugs most probably until the first phase of clinical trials its clients are the pharmaceutical companies with capacity to further develop the product and to bring it to the market. In this way, maintaining the highest visibility of the company is paramount to improve the value of the patented drugs, so that the business model can succeed.

The cost structure of the company will be very simple, due to its simple organizational structure. As follows, the main costs will be the costs related with research and development and will depend on the peace of the investigation. In this phase, the biggest cost the company will have are the Clinical Trials Phase I/II-A, and the success on this phase will delineate the success of the investigation. Regarding the personnel costs, all the workers will have a constant salary and a percentage of the total value earned in the transaction of the patents. With this practice, the company aims to motivate the workers to perform an effective and efficient work, in order to develop a drug with high performance to sell the patent at the highest possible value.

Following this line, the revenue stream of AMS will be based on its ability to generate value from the license of its patents. In this way, the main source of revenues will be the transaction of the patent. Anyhow the company will apply to any other funds raising money to ensure its financial and economic viability like for instance the Bill and Melinda Gates Foundation, which funds the development of anti-malarial drugs as referred before.

9. Marketing

This section of the business plan will be composed by two different parts. The first one corresponds to the marketing strategy of AMS and the second part will briefly describe a possible marketing strategy that a potential buyer of the patent of *Prophyl-ACT* could adopt. At this point, it shall be enhanced that this part only serves to understand the cost structure during the commercialization phase, which will not be performed by AMS, being only a theoretical exercise. However, without this it would not be possible to evaluate the economic viability of the commercialization of the drug and, consequently, the economic viability of AMS.

9.1. AMS Marketing Plan

As mentioned before in this business plan, the success of the company has a great dependability on external entities. Firstly, the company will need to participate in some rounds of investment in order to raise enough funds to start and maintain the business. Additionally, there is a need of collecting knowledge about the last news and methods related with malaria, in order to keep the company as an example of constant innovation. Lastly, due to the out-licensing of the patent, it is important to the company to be in contact with pharmaceutical companies to increase awareness on those companies that will probably buy the patent. During this process, the CEO and the Marketing Manager will have an important role to perform.

Considering what was said above, it can be considered this part as a communication plan instead of a marketing plan, given that the company will not commercialize any product or service. Instead, the company will only sell some assets, in this case patents. Thus, there will not be a segmentation, targeting and positioning, as well as marketing mix, due to the absence of constant cash flows entering the company.

Yet, it is important to specify which will be the strategy of the company at this respect. Therefore, the company, through its CEO and Marketing Manager, will be present on international conferences and other events related with malaria. Additionally, the company shall be present in events related with entrepreneurship and value creation in start-ups, given that there are several investors that go to these events. Finally, the company shall be in other pharmaceutical industry events, in order to establish some contacts with pharmaceutical companies.

9.2. Marketing plan to commercialization

This exercise is performed to have a more accurate cost estimation to present to the buyer of the patent. Thus, the following assumption was made: a company with a well-established sales channel will commercialized the *Prophyl-ACT* so that having the capacity to sell the product in different markets right from the beginning. Therefore, the company will sell the drug on European countries, starting with Portugal, Spain, France and UK, and expanding to other countries in the following years. The company sells the prophylaxis in Europe because this drug is indicated to people that go to endemic malaria countries for short periods. As follows, it will be explained the marketing mix of the commercialization

Product

The product is composed by a tablet of 16 pills that have prophylactic effects. This will allow the body to trick the parasite by sending messages about the low level of food that the parasite supposedly had in the environment. As a consequence, the parasite stops reproducing and fights for surviving.

This drug is composed by already approved compounds for human utilization. Therefore, these compounds are known by having low adverse effects to humans and absence of habituation to them of the body, allowing people to stop consuming quickly.

Place

Prophyl-ACT will be available in pharmacy shops in European countries. People may have access to the medicine there and shall start the treatment two days before the travel.

Promotion

The communication of the drug shall be a combination of a pull and a push strategy. In this way, the company shall advertise in travel magazines or other related newspapers and, at the same time, sales representatives shall maintain a strict relationship with pre-travel doctors because they have an important influence on the final choice of the customer.

Price

The price practiced in the sale of *Prophyl-ACT* shall give the information for customers that the company is providing a premium product. In this way, the company shall practice a higher price than the price of the best competitor product, Malarone. Therefore, the final price to customers shall be around €35.

10. Implementation of the Plan

This section will comprise all the resources that the company will need whilst developing the drug. Thus, there will be a description about the activities to perform during the time-to-market period, the materials and equipment needed to accomplish those activities and the minimum requisites to validate these activities, in order to accomplish the plan.

10.1. Time-to-market

The time-to-market period is directly related with the duration of the R&D phase of a product. As follows, all the legal requisites that a prototype of a drug shall respect are variables that greatly increase this period.

Concerning with the Clinical Trials, there are four phases of submission of a drug that must be approved. However, given that the raw materials are already used and approved in human beings, it is possible to aggregate the clinical trials in three phases – Phase I/II-A; Phase II-B/III and Phase IV. This will shorten the time-to-market period and will decrease the risk subjacent to this project.

Considering what was said above and that the proof of concept will be finished in 2017, it is planned that the company will sell the patent in 2019, after Phase I/II-A, and it is expected that it will be launched in the market in 2023.

Table 3 - Project's Flowchart

2016	2017	2018	2019
Proof of Concept			
		CT Phase I/II-A	
			Out-Licensing Process
		R&D for Other Products	

Source: Author

10.2. Material Needed

The company will need some materials that will be included in the account “Supplies and Service Expenses”. In this account, it will be included different materials used in the company’s activities as well as other services contracted.

Concerning the services, the company will need to outsource lawyer services in the beginning in order to fulfil all the legal requirements to approve in the patent acquisition process. Moreover, the company shall hire an accounting team to prepare the financial statements, a communication plan with mobile phones communication and internet to support

its the daily activities. Furthermore, given that the company will not purchase its own building, it will pay a monthly rent that includes the space based on square meters and the expenditure of water and electricity. Finally, the company must contract insurance services for the vehicle and to other equipment.

Regarding with the materials needed, the company will consume the compounds used in the R&D process. However, these materials can be considered as investment in R&D and, therefore can be depreciated. The company predicts to spend 80.000€ per year in R&D. Moreover, there are some office consumables that are important to use, such as cartridges, paper, pens and other office materials.

10.3. Equipment Needed

The company has to invest in some equipment needed to the R&D Phase and to the management activities in the upcoming years of the project.

Regarding the laboratory equipment, the company will need a Flow Cytometer, one incubator, one fridge, one freezer and pipettes, and the investment in these materials is expected to be 64.551€.

Additionally, the company has to perform the support activities and provide to its management staff the basic equipment. Therefore, the company will purchase one printing machine, two mobile phones, two phones and furniture in an investment of 992.46€ in the first two years. Moreover, the company will need a vehicle to the CEO in order to provide transportation during his short business trips. The vehicle is expected to cost 25.000€

10.4. Implementation Requisites

In order to ensure that the plan will be accomplished and the industrial property of *Prophyl-ACT* will be sold in 2019, there are some implementation requisites to respect.

The first step to start with the plan is to raise enough investment so that the company as capacity to purchase the equipment needed. In this way, the company will need to Fixed Tangible Assets, such as Laboratory equipment of 67.551€, Administrative equipment of 822.23€ and transportation equipment of 25.000€.

Regarding the industrial property that gives protection to the technology, this implies a huge investment to the company. First of all, AMS must contract lawyer services to help in the legal issues implied during the process. Additionally, after the patent approval, the company has to pay an annuity of 10.000€ in order to maintain the patent protection.

Considering the development of the drug, there are two steps that must be completed. The first one is the Proof of Concept that may be finished in the end of 2017 and it is estimated a cost of 300.000€ to pay in the first year. Afterwards, the Clinical Trials Phase I/II-A is the last step before the sale of the patent. This Clinical Trial has a cost estimated in 2.000.000€ to pay in 2018 and may be raised in bank loans to pay after the sale.

11. Financial Forecasts

The Financial Forecasts are one of the most important sections in this business plan given that it will be possible to study the economic viability of the presented project. Following this, the author will provide the explanation of the assumptions that based the forecasting process. Afterwards, it will be presented the financial forecasts of AMS until the moment when the patent is sold to other bigger pharmaceutical company. Finally, the author has to perform the forecasts during the commercialization period, in order to estimate the value of this activity.

11.1. Assumptions

The exercise of financial forecasting is based on some important assumptions that characterize the external environment of the company. In this way, the author uses information from official governmental and public sources, in order to use more accurate values that will have a great impact on the company's performance. To better understand the financial forecasts performed there are some assumptions to be acknowledged:

- The financial forecasts of AMS will be calculated until the patent sale, in 2019, and the financial statements of the commercialization will start on 2016 and finish 5 years after the market entry, in 2027.
- The predicted inflation rates will be 1.49% in 2017, 1.64% in 2018 and 1.76% in 2019 (IMF, 2016). After this period, the author assumes an inflation rate of 2.0% in the 2020-2027 period.
- The author defined an increasing rate in wages above the inflation rate. Therefore, the wages increasing rate will be 2% between 2017-2019 and 2.5% between 2020-2027.
- The interest rate of the Treasury bill (10 years period) of the Portuguese Government is 2.84%.
- The VAT rate applied both in purchases of raw materials and supplies and service expenses, and in the sales is considered 23%.
- The account receivables period and account payables period are both 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 has to pay Average Tax Rate on Profits of 19% and a Balance Local State Tax of 1.5%, which equals to 20.5% of Taxes on Profits;

- The company pays 23.75% of the employee wage to social security whilst the employee pays 11%, which is withheld by the company.
- Each employee pays an Average Income Tax of 14.5% over his salary, which is withheld by the company;
- The company pays 1% over each employee wage as Accidents Insurance;
- To each worker, the company pays a food allowance of 4.27€ per day.
- The company will distribute 2% of the patent sale by its workers, as variable salary. This will happen in 2019.
- AMS is funded with 100% of equity and 0% of 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%, a β of 1.02. The Weighted Average Cost of Capital is 7.72%.
- The author considered a 3% Interest Rate in short run financing and 4% in long run bank loans.
- The Continuation Value of the project is not calculated in these financial forecasts given that the patent will be sold in 2019, and it is not certain that the company will be capable to develop new drugs.

11.2. Financial Forecasts for AntiMalarial Solutions

Cost Projections

Given that the AMS will not commercialize any product, the company will not have any sales projection. Therefore, the company will not have any Cost of Goods Sold, meaning that the company shall only forecast the Supplies and Service Expenses.

Table 4 - COGS and Supplies and Service Expenses, AMS

Costs of Goods Sold and Supplies and Services Expenses - Current Prices					
		2016	2017	2018	2019
Accumulated Inflation Factor		1,000	1,016	1,036	1,057
Supplies and Services Expenses	Unit Cost	0	1	2	3
Office Rent		14 400,00 €	14 630,40 €	14 923,01 €	15 221,47 €
Communication Plan		300,00 €	304,80 €	310,90 €	317,11 €
Diesel	3 125,00 €	3 125,00 €	3 175,00 €	3 238,50 €	3 303,27 €
Car insurance	600,00 €	600,00 €	609,60 €	621,79 €	634,23 €
Lawyers Fees		8 000,00 €	8 128,00 €		
Accounting Team		7 000,00 €	7 112,00 €	7 254,24 €	7 399,32 €
Plain Tickets		10 000,00 €	10 160,00 €	10 363,20 €	10 570,46 €
Hotels		20 000,00 €	20 320,00 €	20 726,40 €	21 140,93 €
Representation Meals		3 000,00 €	3 048,00 €	3 108,96 €	3 171,14 €
Conferences		10 000,00 €	10 160,00 €	10 363,20 €	10 570,46 €
Office Consumables		5 000,00 €	5 080,00 €	5 181,60 €	5 285,23 €
IP Annuities		10 000,00 €	10 000,00 €	10 000,00 €	10 000,00 €
Total SSE Purchases		91 425,00 €	92 727,80 €	86 091,80 €	87 613,63 €

Source: Author

Investment in Net Working Capital

Table 5 - Net Working Capital, AMS

NET WORKING CAPITAL - CURRENT PRICES, Y0					
	Period	2016	2017	2018	2019
FIRM'S NEEDS					
Account's Receivables	**30**				
Stocks	**30**				
Vat to Receive	**30**	9 164,68 €	4 442,21 €	44 528,43 €	- €
TOTAL NEEDS OF THE FIRM		**9 164,68 €**	**4 442,21 €**	**44 528,43 €**	**- €**
FIRM'S RESOURCES					
Account payables	**30**	7 514,38 €	7 621,46 €	7 076,04 €	7 201,12 €
GOPE (SS)	**30**	4 569,60 €	5 567,20 €	5 706,38 €	9 446,78 €
GOPE (Income Taxes)	**30**	1 906,74 €	2 323,01 €	2 381,08 €	3 941,82 €
TOTAL RESOURCES OF THE FIRM		**13 990,73 €**	**15 511,67 €**	**15 163,50 €**	**20 589,72 €**
NEEDS OF NET WORKING CAPITAL		**- 4 826,05 €**	**- 11 069,46 €**	**29 364,93 €**	**- 20 589,72 €**
INVESTMENT IN NET WORKING CAPITAL		**- 4 826,05 €**	**- 6 243,41 €**	**40 434,39 €**	**- 49 954,65 €**

Source: Author

Although that these values may look strange at a first glance, there is a reason why the company has only in one year needs of investment in net working capital. Given that the company does not have commercial activity, the accounts of stocks and Account Receivables are zero and the value that the company will receive in VAT is low. However, this value increases in 2018 due to the high investments on R&D that the company has to do. This means that the company do not need to allocate financial resources to ensure the current activities of the company.

Cash Flow Analysis

Table 6 - Cash Flow Statement, AMS

CASH FLOW STATEMENT - CURRENT PRICES					
	2016	2017	2018	2019
FINANCIAL RESOURCES				
NOPAT	- 296 180,32 €	- 342 089,12 €	- 341 532,14 €	4 895 839,57 €
Uninvestment in NWC	4 826,05 €	6 243,41 €	- €	49 954,65 €
TOTAL FINANCIAL RESOURCES	**- 291 354,27 €**	**- 335 845,70 €**	**- 341 532,14 €**	**4 945 794,22 €**
FINANCIAL NEEDS				
Investment in Fixed Assets	393 373,23 €	142 258,77 €	2 269 397,59 €	- €
Investment in NWC	- €	- €	40 434,39 €	- €
TOTAL FINANCIAL NEEDS	**393 373,23 €**	**142 258,77 €**	**2 309 831,98 €**	**- €**
CASH FLOW OF THE PROJECT	**- 684 727,50 €**	**- 478 104,47 €**	**- 2 651 364,12 €**	**4 945 794,22 €**
ACCUMULATED CASH FLOW	**- 684 727,50 €**	**- 1 162 831,98 €**	**- 3 814 196,10 €**	**1 131 598,12 €**

Source: Author

Given that the company does not have to invest in NWC, except in 2018, this will free funds and improve the Cash Flows of the project. However, there are some huge investments,

mainly in 2018, that will reduce the Cash Flows. Therefore, the activity of the company will only have positive cash flows in 2019, after the patent sale to other pharmaceutical company.

Economic Valuation of the Project

Table 7 - Project´s Evaluation, AMS

PROJECT'S EVALUATION	0	1	2	3
Cash Flow of the Project	- 684 727,50 €	- 478 104,47 €	- 2 651 364,12 €	4 945 794,22 €
Accumulated Inflation Factor	**1,0000**	**1,0149**	**1,0315**	**1,0497**
Deflated Cash Flow	- 684 727,50 €	- 471 085,30 €	- 2 570 286,09 €	4 711 628,45 €
WACC	**8,35%**	**6,76%**	**7,50%**	**6,47%**
Discount Factor	1,0000	1,0676	1,1476	1,2219
Discounted Cash Flow	- 684 727,50 €	- 441 267,46 €	- 2 239 664,86 €	3 855 927,01 €
Accumulated Discounted Cash Flow	- 684 727,50 €	- 1 125 994,97 €	- 3 365 659,83 €	490 267,18 €
Net Present Value of the Project	490 267,18 €			
Internal Rate of Return	16,43%			
Payback Period of Project	3,87			

Source: Author

The method used in the economic valuation of the project allows the investors to decide whereas a project is worth or not of investment. In this way, the Net Present Value, which consists on the cumulative value of the discounted cash flows of the project, is a fundamental criteria to present to possible investors. Considered the value presented of €490267.18, this project is worth of investment and shall continue to the implementation phase.

Provisional Income Statement

Table 8 - Income Statement, AMS

INCOME STATEMENT - CURRENT PRICES	2016	2017	2018	2019
Sales				6 298 197,24 €
Costs of Goods Sold				
Gross Margin	**- €**	**- €**	**- €**	**6 298 197,24 €**
External Services and Supplies	91 425,00 €	92 727,80 €	86 091,80 €	87 613,63 €
Personnel Costs	204 755,32 €	249 361,32 €	255 440,35 €	418 811,38 €
EBITDA	**- 296 180,32 €**	**- 342 089,12 €**	**- 341 532,14 €**	**5 791 772,24 €**
				0,92 €
Depreciations	31 051,50 €	61 192,05 €	174 661,93 €	174 661,93 €
EARNINGS BEFORE TAXES	**- 327 231,83 €**	**- 403 281,17 €**	**- 516 194,07 €**	**5 617 110,31 €**
Deductible Losses	- €	- 327 231,83 €	- 730 512,99 €	- 1 246 707,07 €
Taxable Amount (Matéria Colectável)	- 327 231,83 €	- 730 512,99 €	- 1 246 707,07 €	4 370 403,24 €
Taxes on Profits	- €	- €	- €	895 932,66 €
NET INCOME	**- 327 231,83 €**	**- 403 281,17 €**	**- 516 194,07 €**	**4 721 177,64 €**
NOPAT	**- 296 180,32 €**	**- 342 089,12 €**	**- 341 532,14 €**	**4 895 839,57 €**

Source: Author

In this financial statement, it is important to highlight and explain the variance between the sales of 2018 and the sales of 2019. In the last year of this project, the 6298197.24€ in sales come from the sale of the patent, which is 6000000 at prices of 2016.

Financial Plan

Table 9 - Financial Plan, AMS

FINANCIAL PLAN - CURRENT PRICES					
		2016	2017	2018	2019
FINANCIAL RESOURCES					
EBITDA		- 296 180,32 €	- 342 089,12 €	- 341 532,14 €	5 791 772,24 €
Uninvestment in NWC		4 826,05 €	6 243,41 €	- €	49 954,65 €
Shared Capital		1 000 000,00 €	- €	- €	- €
Other Equity Instruments		- €	412 617,74 €	2 063 088,72 €	- 2 475 706,46 €
Financial Aplication Recovery		- €	- €	242 164,31 €	- €
Return of Financial Apllications		- €	- €	3 632,46 €	- €
TOTAL FINANCIAL RESOURCES		**708 645,73 €**	**76 772,04 €**	**1 967 353,35 €**	**3 366 020,42 €**
FINANCIAL NEEDS					
Investment in Fixed Assets		393 373,23 €	142 258,77 €	2 269 397,59 €	- €
Investment in NWC		- €	- €	40 434,39 €	- €
Payout		- €	- €	- €	- €
GOPE - Taxes on Profits		- €	- €	- €	- €
Reimbursment of Short-run Financial Applications		- €	- €	- €	353 276,15 €
Taxes on Profits of Financial Applications		- €	- €	744,66 €	- €
TOTAL FINANCIAL NEEDS		**393 373,23 €**	**142 258,77 €**	**2 310 576,63 €**	**353 276,15 €**
TARGETED VALUE	**30**	**315 272,50 €**	**7 621,46 €**	**7 076,04 €**	**7 201,12 €**
VALUE TO FINANCE		**- €**	**- €**	**342 677,86 €**	**- €**
VALUE TO APPLY		**- €**	**242 164,31 €**	**- €**	**3 012 619,19 €**
Short-Run Financing		- €	- €	353 276,15 €	- €
Interests of Short-Run Financing		- €	- €	10 598,28 €	- €
CASH AND EQUIVALENTS		**315 272,50 €**	**- 307 651,03 €**	**- 545,42 €**	**125,08 €**
CUMULATIVE CASH		**315 272,50 €**	**7 621,46 €**	**7 076,04 €**	**7 201,12 €**

Source: Author

Provisional Balance Sheet

Table 10 - Balance Sheet, AMS

BALANCE SHEET - CURRENT PRICES	2016	2017	2018	2019
ASSETS				
Non-current Assets				
Intangible Assets				
R&D Expenses	285 000,00 €	324 130,71 €	2 437 997,13 €	2 282 465,95 €
Patent	- €	57 849,30 €	54 804,60 €	51 759,90 €
Sub-Total	**285 000,00 €**	**381 980,01 €**	**2 492 801,73 €**	**2 334 225,85 €**
Tangible Assets				
Transportation Equipment	18 750,00 €	12 500,00 €	6 250,00 €	- €
Laboratory Equipment	57 904,72 €	48 258,43 €	38 612,15 €	28 965,87 €
Administrative Equipment	667,01 €	650,00 €	460,23 €	270,45 €
Sub-Total	**77 321,73 €**	**61 408,44 €**	**45 322,38 €**	**29 236,32 €**
Current Assets				
Inventory	- €	- €	- €	- €
Account Receivables	- €	- €	- €	- €
GOPE	9 164,68 €	4 442,21 €	44 528,43 €	- €
Financial applications	- €	242 164,31 €	- €	3 012 619,19 €
Cash and Equivalents	315 272,50 €	7 621,46 €	7 076,04 €	7 201,12 €
Sub-Total	**324 437,17 €**	**254 227,98 €**	**51 604,47 €**	**3 019 820,31 €**
TOTAL DAS ASSETS	**686 758,90 €**	**697 616,42 €**	**2 589 728,57 €**	**5 383 282,49 €**
EQUITY				
Shared Capital	1 000 000,00 €	1 000 000,00 €	1 000 000,00 €	1 000 000,00 €
Other Equity Instruments	- €	412 617,74 €	2 475 706,46 €	- €
Reserves	- €	- €	- €	50 000,00 €
Reserves and Retained Earnings	- €	- 327 231,83 €	- 730 512,99 €	- 1 254 417,54 €
Retained Earnings	- 327 231,83 €	- 403 281,17 €	- 523 904,55 €	2 938 883,92 €
Payout	- €	- €	- €	1 734 466,37 €
TOTAL EQUITY	**672 768,17 €**	**682 104,75 €**	**2 221 288,92 €**	**4 468 932,75 €**
LIABILITIES				
Long Run Liabilities				
Bank Loans	- €	- €	- €	- €
Sub-Total	**- €**	**- €**	**- €**	**- €**
Short Run Liabilities				
Account Payables	7 514,38 €	7 621,46 €	7 076,04 €	7 201,12 €
GOPE	6 476,34 €	7 890,21 €	8 087,46 €	13 388,60 €
Taxes on Profits	- €	- €	- €	893 760,02 €
Bank Loans				
Bank Loans in Euros	- €	- €	- €	- €
Short-Run Financing	- €	- €	353 276,15 €	- €
Sub-Total	**13 990,73 €**	**15 511,67 €**	**368 439,65 €**	**914 349,74 €**
TOTAL LIABILITIES	**13 990,73 €**	**15 511,67 €**	**368 439,65 €**	**914 349,74 €**
TOTAL EQUITY AND LIABILITES	**686 758,90 €**	**697 616,42 €**	**2 589 728,57 €**	**5 383 282,49 €**

Source: Author

Ratios

Financial Ratios give important information about the performance of the company. In this situation, the company only will generate profits in 2019 because it is the year when the

patent will be sold. Therefore, the importance of this year in all the company's activity will be crucial to understand if the project being developed is viable or not. In this way, the following ratios will quantify the situation of the company after licensing the patent.

Table 11 - Economic Ratios, AMS

Economic Ratios	2019
Return On Investment (ROI)	88%
Return on Assets (ROA)	104%
Return on Equity (ROE)	106%

Source: Author

The economic ratios offer an idea about the economic performance of the business and the viability of the project. In this way, ROI of 88% indicates that each euro invested in this project has a return of 0.88€ to the investors. Considering the 104% of ROA, each euro hold in the assets of the company generate 1.04€ as turnover. Finally, each euro invested in the company by shareholders have a return of 1.06€ in the end of 2019. These ratios were only calculated in 2019 given that it is the only year when the company generates profit.

Table 12 - Financial Ratios

Financial Ratios	2019
Equity Ratio	83%
Debt-to-Equity Ratio	20%

Source: Author

The financial ratios provide information about the financial health of the company. In this way, the Equity Ratio, that relates the equity with the total assets, gives an idea about how leveraged a company is. In this way, 83% of the assets are financed by equity, meaning that the company has a low dependence of bank loans and other debt instruments. Regarding the Debt-to-Equity Ratio, this indicates again the financial leverage of the company. In this case, the company as five times more debt than equity, meaning that AMS is in a healthy situation.

Table 13 - Liquidity Ratio, AMS

Liquidity Ratios	2019
Current Ratios	330%

Source: Author

Finally, the liquidity ratio reveals the capacity of the company to pay its liabilities. Focusing in the Current Ratio, that relates the current assets with the current liabilities, AMS has three times more current assets than current liabilities, meaning that the company has the capacity to meet all the short-run liabilities with the current assets.

11.3. Financial Forecasts for the commercialization

This section is important in the current business plan because it will provide information about the product performance during the commercialization phase. In this way, the author will disclose information about the viability of this product, in order to give justified arguments during the negotiations with the buyer of the patent.

Cost Projection

Table 14 - COGS and Supplies and Service Expenses, Commercialization

Costs of Goods Sold and Supplies and Service Expenses - Current Prices													
		2016	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**
Costs of Goods Sold	**Period**	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
Accumulated Inflation Factor		**1,000**	**1,016**	**1,036**	**1,057**	**1,078**	**1,100**	**1,122**	**1,144**	**1,167**	**1,190**	**1,214**	**1,238**
Quantity Sold		0	0	0	0	0	0	0	937495	1239092	1417140	1571204	1802988
Unit COGS		€ 9,85	€ 10,01	€ 10,21	€ 10,41	€ 10,62	€ 10,83	€ 11,05	€ 11,27	€ 11,49	€ 11,72	€ 11,96	€ 12,20
COGS		€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ 12 088 427,21	€ 16 622 821,30	€ 19 779 453,28	€ 22 815 734,07	€ 27 239 244,00
Final Inventory	0	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ 1 136 823,20	€ 1 594 512,90	€ 1 935 253,03	€ 2 276 974,10	€ 2 772 802,05
Initial Inventory		€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ 1 136 823,20	€ 1 594 512,90	€ 1 935 253,03	€ 2 276 974,10
Purchase of COGS		**€ -**	**€ -**	**€ -**	**€ -**	**€ -**	**€ -**	**€ -**	**€ 13 225 250,41**	**€ 17 080 511,00**	**€ 20 120 193,41**	**€ 23 157 455,14**	**€ 27 735 071,95**
Supplies and Service Expenses	**Unit Cost**	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
Office Rent	€ 25 000,00	€ 25 000,00	€ 25 400,00	€ 25 908,00	€ 26 426,16	€ 26 954,68	€ 27 493,78	€ 28 043,65	€ 28 604,53	€ 29 176,62	€ 29 760,15	€ 30 355,35	€ 30 962,46
Communication Plan	€ 700,00	€ 700,00	€ 711,20	€ 725,42	€ 739,93	€ 754,73	€ 769,83	€ 785,22	€ 800,93	€ 816,95	€ 833,28	€ 849,95	€ 866,95
Diesel	€ 4 000,00	€ 4 000,00	€ 4 064,00	€ 4 145,28	€ 4 228,19	€ 4 312,75	€ 4 399,00	€ 4 486,98	€ 4 576,72	€ 4 668,26	€ 4 761,62	€ 4 856,86	€ 4 953,99
Car insurance	€ 600,00	€ 600,00	€ 1 219,20	€ 1 243,58	€ 1 268,46	€ 1 293,82	€ 1 319,70	€ 2 019,14	€ 2 746,03	€ 2 800,96	€ 2 856,97	€ 2 914,11	€ 2 972,40
Lawyers Fees		€ 8 000,00	€ 8 000,00	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ -
Accounting Team		€ 7 000,00	€ 7 112,00	€ 7 254,24	€ 7 399,32	€ 7 547,31	€ 7 698,26	€ 7 852,22	€ 8 009,27	€ 8 169,45	€ 8 332,84	€ 8 499,50	€ 8 669,49
Plain Tickets	€ 12 000,00	€ 12 000,00	€ 12 192,00	€ 12 435,84	€ 12 684,56	€ 12 938,25	€ 13 197,01	€ 13 460,95	€ 13 730,17	€ 14 004,78	€ 14 284,87	€ 14 570,57	€ 14 861,98
Hotels	€ 20 000,00	€ 20 000,00	€ 20 320,00	€ 20 726,40	€ 21 140,93	€ 21 563,75	€ 21 995,02	€ 22 434,92	€ 45 767,24	€ 46 682,59	€ 47 616,24	€ 48 568,56	€ 49 539,93
Representation Meals	€ 3 000,00	€ 3 000,00	€ 3 048,00	€ 3 108,96	€ 3 171,14	€ 3 234,56	€ 3 299,25	€ 3 365,24	€ 3 432,54	€ 3 501,19	€ 3 571,22	€ 3 642,64	€ 3 715,49
Conferences	€ 10 000,00	€ 10 000,00	€ 10 160,00	€ 10 363,20	€ 10 570,46	€ 10 781,87	€ 10 997,51	€ 11 217,46	€ 11 441,81	€ 11 670,65	€ 11 904,06	€ 12 142,14	€ 12 384,98
Office Consumables	€ 5 000,00	€ 5 000,00	€ 5 080,00	€ 5 181,60	€ 5 285,23	€ 5 390,94	€ 5 498,76	€ 5 608,73	€ 5 720,91	€ 5 835,32	€ 5 952,03	€ 6 071,07	€ 6 192,49
IP Annuities	€ 10 000,00	€ 10 000,00	€ 10 000,00	€ 10 000,00	€ 10 000,00	€ 10 000,00	€ 10 000,00	€ 10 000,00	€ 10 000,00	€ 10 000,00	€ 10 000,00	€ 10 000,00	€ 10 000,00
Total SSE Purchases		**€ 105 300,00**	**€ 107 306,40**	**€ 101 092,53**	**€ 102 914,38**	**€ 104 772,67**	**€ 106 668,12**	**€ 109 274,53**	**€ 134 830,15**	**€ 137 326,75**	**€ 139 873,29**	**€ 142 470,75**	**€ 145 120,17**
Total Purchases (SSE + COGS)		**€ 105 300,00**	**€ 107 306,40**	**€ 101 092,53**	**€ 102 914,38**	**€ 104 772,67**	**€ 106 668,12**	**€ 109 274,53**	**€ 13 360 080,56**	**€ 17 217 837,75**	**€ 20 260 066,70**	**€ 23 299 925,89**	**€ 27 880 192,11**

Source: Author

Sales Projection

Table 15 - Total Revenues, Commercialization

REVENUES - CURRENT PRICES												
		2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
Accumulated Inflation Factor		**1,0000**	**1,0160**	**1,0363**	**1,0570**	**1,0782**	**1,0998**	**1,1217**	**1,1442**	**1,1671**	**1,1904**	**1,2142**	**1,2385**
Prophyl-ACT Sold									1 968 741	2 631 629	3 089 943	3 576 991	4 347 852
Unit Selling Price	21,89 €												
Total Revenues		**- €**	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**	**49 309 328,22 €**	**67 230 344,31 €**	**80 517 690,91 €**	**95 073 364,41 €**	**117 873 434,95 €**
Account Receivables		**- €**	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**	**4 109 110,69 €**	**5 602 528,69 €**	**6 709 807,58 €**	**7 922 780,37 €**	**9 822 786,25 €**
Growth Rate										**36%**	**20%**	**18%**	**24%**

Source: Author

The forecasting of sales was based on the number of cases of imported malaria in European Union. The focus was EU due to the similar legislations between countries. The countries where the product will be sold were chosen according the number of cases of malaria per capita, excluding Portugal. Those countries where the product will be sold are Portugal, Spain, France and United Kingdom, in 2023, Germany and Italy, in 2024, and Belgium and Netherlands in 2025. It was considered a penetration rate of 4.2% based on the great performance of Harvoni, a recent drug introduced by Gilead Sciences directed to treat Hepatitis C.

Investment in Net Working Capital

Table 16 - Net Working Capital, Commercialization

NET WORKING CAPITAL - CURRENT PRICES													
	Prazo	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
FIRM'S NEEDS													
Account's Receivables	**30**	- €	- €	- €	- €	- €	- €	- €	4 109 110,69 €	5 602 528,69 €	6 709 807,58 €	7 922 780,37 €	9 822 786,25 €
Stocks	**30**	- €	- €	- €	- €	- €	- €	- €	1 136 823,20 €	1 594 512,90 €	1 935 253,03 €	2 276 974,10 €	2 772 802,05 €
Vat to Receive	**30**	3 755,74 €	2 511,97 €	119 458,17 €	1 945,50 €	165 547,56 €	2 550,75 €	2 602,59 €	- €	- €	- €	- €	- €
TOTAL NEEDS OF THE FIRM		**3 755,74 €**	**2 511,97 €**	**119 458,17 €**	**1 945,50 €**	**165 547,56 €**	**2 550,75 €**	**2 602,59 €**	**5 245 933,89 €**	**7 197 041,59 €**	**8 645 060,60 €**	**10 199 754,47 €**	**12 595 588,29 €**
FIRM'S RESOURCES													
Account payables	**30**	8 654,79 €	8 942,20 €	8 424,38 €	8 576,20 €	8 731,06 €	8 889,01 €	9 106,21 €	1 113 340,05 €	1 434 819,81 €	1 688 338,89 €	1 941 660,49 €	2 323 349,34 €
GOPE (SS)	**30**	4 569,60 €	5 567,20 €	6 390,39 €	6 550,15 €	6 713,90 €	6 881,75 €	8 306,52 €	43 567,97 €	57 757,35 €	68 532,62 €	77 523,45 €	91 244,03 €
GOPE (Income Taxes)	**30**	1 906,74 €	2 323,01 €	2 666,49 €	2 733,15 €	2 801,48 €	2 871,52 €	3 466,03 €	18 179,44 €	24 100,19 €	28 596,35 €	32 347,91 €	38 073,05 €
TOTAL RESOURCES OF THE FIRM		**15 131,14 €**	**16 832,41 €**	**17 481,26 €**	**17 859,50 €**	**18 246,44 €**	**18 642,28 €**	**20 878,76 €**	**1 175 087,46 €**	**1 516 677,36 €**	**1 785 467,86 €**	**2 051 531,86 €**	**2 452 666,42 €**
NEEDS OF NET WORKING CAPITAL		**- 11 375,40 €**	**- 14 320,44 €**	**101 976,91 €**	**- 15 913,99 €**	**147 301,12 €**	**- 16 091,53 €**	**- 18 276,17 €**	**4 070 846,43 €**	**5 680 364,24 €**	**6 859 592,74 €**	**8 148 222,61 €**	**10 142 921,87 €**
INVESTMENT IN NET WORKING CAPITAL		**- 11 375,40 €**	**- 2 945,05 €**	**116 297,36 €**	**- 117 890,91 €**	**163 215,11 €**	**- 163 392,65 €**	**- 2 184,64 €**	**4 089 122,59 €**	**1 609 517,81 €**	**1 179 228,51 €**	**1 288 629,87 €**	**1 994 699,26 €**

Source: Author

The company only have to invest in NWC after entering in the market. This is due to the big difference between the amount in account receivables and account payables. The impact of the values to pay or receive from the Government is insignificant after the launch of drug in the market.

Cash Flow Analysis

Table 17 - Cash Flow Statement, Commercialization

CASH-FLOW STATEMENT - CURRENT PRICES												
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
FINANCIAL RESOURCES												
NOPAT	- 310 055,32 €	- 356 667,72 €	- 387 441,75 €	- 396 241,50 €	- 405 252,13 €	- 414 478,74 €	- 480 348,77 €	26 974 853,20 €	37 903 213,49 €	45 672 408,96 €	54 515 406,75 €	68 522 258,17 €
Uninvestment in NWC	11 375,40 €	2 945,05 €	- €	117 890,91 €	- €	163 392,65 €	2 184,64 €	- €	- €	- €	- €	- €
TOTAL FINANCIAL RESOURCES	**- 298 679,93 €**	**- 353 722,67 €**	**- 387 441,75 €**	**- 278 350,59 €**	**- 405 252,13 €**	**- 251 086,09 €**	**- 478 164,13 €**	**26 974 853,20 €**	**37 903 213,49 €**	**45 672 408,96 €**	**54 515 406,75 €**	**68 522 258,17 €**
FINANCIAL NEEDS												
Investment in Fixed Assets	93 373,23 €	25 572,95 €	6 218 071,57 €	- €	8 652 453,31 €	28 262,76 €	28 398,67 €	106 731,84 €	29 661,55 €	30 766,62 €	30 562,05 €	31 324,74 €
Investment in NWC	- €	- €	116 297,36 €	- €	163 215,11 €	- €	- €	4 089 122,59 €	1 609 517,81 €	1 179 228,51 €	1 288 629,87 €	1 994 699,26 €
TOTAL FINANCIAL NEEDS	**93 373,23 €**	**25 572,95 €**	**6 334 368,93 €**	**- €**	**8 815 668,42 €**	**28 262,76 €**	**28 398,67 €**	**4 195 854,43 €**	**1 639 179,36 €**	**1 209 995,13 €**	**1 319 191,91 €**	**2 026 024,00 €**
CASH FLOW OF THE PROJECT	**- 392 053,16 €**	**- 379 295,62 €**	**- 6 721 810,68 €**	**- 278 350,59 €**	**- 9 220 920,55 €**	**- 279 348,84 €**	**- 506 562,80 €**	**22 778 998,77 €**	**36 264 034,13 €**	**44 462 413,83 €**	**53 196 214,83 €**	**66 496 234,17 €**
ACCUMULATED CASH FLOW	**- 392 053,16 €**	**- 379 295,62 €**	**- 6 721 810,68 €**	**- 278 350,59 €**	**- 9 220 920,55 €**	**- 279 348,84 €**	**- 506 562,80 €**	**22 778 998,77 €**	**36 264 034,13 €**	**44 462 413,83 €**	**53 196 214,83 €**	**66 496 234,17 €**

Source: Author

In this topic, it is important to enhance the impact of sales in the Cash Flows of the company. In this way, the first year with positive CF is 2023 which is the first year of sales. Additionally, in 2018 and 2020, there is a high impact of the expenses on R&D on the CF that correspond to the Clinical Trials phase II/III-B and Clinical Trials phase IV.

Provisional Income Statement

Table 18 - Income Statement, Commercialization

INCOME STATEMENT - CURRENT PRICES												
	2016	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**
Sales	- €	- €	- €	- €	- €	- €	- €	49 309 328,22 €	67 230 344,31 €	80 517 690,91 €	95 073 364,41 €	117 873 434,95 €
Costs of Goods Sold	- €	- €	- €	- €	- €	- €	- €	13 225 250,41 €	17 080 511,00 €	20 120 193,41 €	23 157 455,14 €	27 735 071,95 €
Gross Margin	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**	**36 084 077,81 €**	**50 149 833,31 €**	**60 397 497,50 €**	**71 915 909,27 €**	**90 138 363,01 €**
External Services and Supplies	105 300,00 €	107 306,40 €	101 092,53 €	102 914,38 €	104 772,67 €	106 668,12 €	109 274,53 €	134 830,15 €	137 326,75 €	139 873,29 €	142 470,75 €	145 120,17 €
Personnel Costs	204 755,32 €	249 361,32 €	286 349,23 €	293 327,12 €	300 479,47 €	307 810,62 €	371 074,24 €	1 915 338,28 €	2 537 161,10 €	3 009 864,20 €	3 402 560,68 €	4 001 840,84 €
EBITDA	**- 310 055,32 €**	**- 356 667,72 €**	**- 387 441,75 €**	**- 396 241,50 €**	**- 405 252,13 €**	**- 414 478,74 €**	**- 480 348,77 €**	**34 033 909,38 €**	**47 475 345,46 €**	**57 247 760,02 €**	**68 370 877,84 €**	**85 991 402,00 €**
Depreciations	16 051,50 €	22 436,09 €	333 362,41 €	333 365,56 €	765 129,17 €	765 666,56 €	772 713,89 €	780 987,77 €	782 018,80 €	782 632,89 €	783 213,96 €	776 066,25 €
EBT	**- 326 106,83 €**	**- 379 103,81 €**	**- 720 804,16 €**	**- 729 607,07 €**	**- 1 170 381,30 €**	**- 1 180 145,30 €**	**- 1 253 062,65 €**	**33 252 921,61 €**	**46 693 326,66 €**	**56 465 127,13 €**	**67 587 663,88 €**	**85 215 335,75 €**
Deductible Losses	- €	- 326 106,83 €	- 52 996,98 €	- 667 807,18 €	- 61 799,89 €	- 1 108 581,41 €	- 71 563,89 €	- 1 181 498,77 €	- €	- €	- €	- €
Taxable Amount (Matéria Colectável)	- 326 106,83 €	- 52 996,98 €	- 667 807,18 €	- 61 799,89 €	- 1 108 581,41 €	- 71 563,89 €	- 1 181 498,77 €	34 434 420,38 €	46 693 326,66 €	56 465 127,13 €	67 587 663,88 €	85 215 335,75 €
Taxes on Profits	- €	- €	- €	- €	- €	- €	- €	7 059 056,18 €	9 572 131,97 €	11 575 351,06 €	13 855 471,10 €	17 469 143,83 €
NET INCOME	**- 326 106,83 €**	**- 379 103,81 €**	**- 720 804,16 €**	**- 729 607,07 €**	**- 1 170 381,30 €**	**- 1 180 145,30 €**	**- 1 253 062,65 €**	**26 193 865,43 €**	**37 121 194,70 €**	**44 889 776,07 €**	**53 732 192,78 €**	**67 746 191,92 €**
NOPAT	**- 310 055,32 €**	**- 356 667,72 €**	**- 387 441,75 €**	**- 396 241,50 €**	**- 405 252,13 €**	**- 414 478,74 €**	**- 480 348,77 €**	**26 974 853,20 €**	**37 903 213,49 €**	**45 672 408,96 €**	**54 515 406,75 €**	**68 522 258,17 €**

Source: Author

Financial Plan

Table 19 - Financial Plan, Commercialization

FINANCIAL PLAN - CURRENT PRICES												
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
FINANCIAL RESOURCES												
EBITDA	- 310 055,32 €	- 356 667,72 €	- 387 441,75 €	- 396 241,50 €	- 405 252,13 €	- 414 478,74 €	- 480 348,77 €	34 033 909,38 €	47 475 345,46 €	57 247 760,02 €	68 370 877,84 €	85 991 402,00 €
Uninvestment in NWC	11 375,40 €	2 945,05 €	- €	117 890,91 €	- €	163 392,65 €	2 184,64 €	- €	- €	- €	- €	- €
Shared Capital	5 000 000,00 €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
Other Equity Instruments	- €	- €	- €	- €	- €	30 000,00 €	1 500 000,00 €	- 1 530 000,00 €	- €	- €	- €	- €
Bank Loans in Euros	8 000 000,00 €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
Financial Aplication Recovery	- €	- €	11 099 996,43 €	3 422 388,29 €	2 129 360,41 €	- €	- €	- €	17 230 247,91 €	50 106 596,20 €	84 833 250,73 €	126 621 370,73 €
Return of Financial Apllications	- €	- €	166 499,95 €	51 335,82 €	31 940,41 €	- €	- €	- €	258 453,72 €	751 598,94 €	1 272 498,76 €	1 899 320,56 €
TOTAL FINANCIAL RESOURCES	**12 701 320,07 €**	**- 353 722,67 €**	**10 879 054,62 €**	**3 195 373,52 €**	**1 756 048,68 €**	**- 221 086,09 €**	**1 021 835,87 €**	**32 503 909,38 €**	**64 964 047,08 €**	**108 105 955,17 €**	**154 476 627,33 €**	**214 512 093,28 €**
FINANCIAL NEEDS												
Investment in Fixed Assets	93 373,23 €	25 572,95 €	6 218 071,57 €	- €	8 652 453,31 €	28 262,76 €	28 398,67 €	106 731,84 €	29 661,55 €	30 766,62 €	30 562,05 €	31 324,74 €
Investment in NWC	- €	- €	116 297,36 €	- €	163 215,11 €	- €	- €	4 089 122,59 €	1 609 517,81 €	1 179 228,51 €	1 288 629,87 €	1 994 699,26 €
Payout	- €	- €	- €	- €	- €	- €	- €	- €	6 039 876,86 €	11 175 103,62 €	13 630 925,17 €	16 415 516,79 €
GOPE	- €	- €	- €	- €	- €	- €	- €	- €	5 140 304,30 €	9 552 451,97 €	11 562 231,06 €	13 848 911,10 €
Reimbursment of Bank Loans	- €	800 000,00 €	800 000,00 €	800 000,00 €	800 000,00 €	800 000,00 €	800 000,00 €	800 000,00 €	800 000,00 €	800 000,00 €	800 000,00 €	- €
Reimbursment of Short-run Financing	- €	- €	- €	- €	- €	8 340 533,26 €	9 878 386,44 €	10 149 592,81 €	- €	- €	- €	- €
Interests of Bank Loans	- €	320 000,00 €	288 000,00 €	256 000,00 €	224 000,00 €	192 000,00 €	160 000,00 €	128 000,00 €	96 000,00 €	64 000,00 €	32 000,00 €	- €
Taxes on revenues from financial applications	- €	- €	34 132,49 €	10 523,84 €	6 547,78 €	- €	- €	- €	52 983,01 €	154 077,78 €	260 862,25 €	389 360,71 €
TOTAL FINANCIAL NEEDS	**93 373,23 €**	**1 145 572,95 €**	**7 456 501,42 €**	**1 066 523,84 €**	**9 846 216,21 €**	**9 360 796,02 €**	**10 866 785,11 €**	**15 273 447,25 €**	**13 768 343,54 €**	**22 955 628,50 €**	**27 605 210,39 €**	**32 679 812,60 €**
TARGETED VALUE	**30 12 607 946,84 €**	**8 654,79 €**	**8 819,70 €**	**8 308,97 €**	**8 458,72 €**	**8 611,45 €**	**8 767,24 €**	**8 981,47 €**	**1 098 088,81 €**	**1 415 164,75 €**	**1 665 210,96 €**	**1 915 062,40 €**
VALUE TO FINANCE	**- €**	**- €**	**- €**	**- €**	**8 090 317,27 €**	**9 582 034,84 €**	**9 845 105,03 €**	**- €**	**- €**	**- €**	**- €**	**- €**
VALUE TO APPLY	**- €**	**11 099 996,43 €**	**3 422 388,29 €**	**2 129 360,41 €**	**- €**	**- €**	**- €**	**17 230 247,91 €**	**50 106 596,20 €**	**84 833 250,73 €**	**126 621 370,73 €**	**181 582 429,24 €**
Short-run Financing	- €	- €	- €	- €	8 340 533,26 €	9 878 386,44 €	10 149 592,81 €	- €	- €	- €	- €	- €
Interests of Short-run Financing	- €	- €	- €	- €	250 216,00 €	296 351,59 €	304 487,78 €	- €	- €	- €	- €	- €
CASH AND EQUIVALENTS	**12 607 946,84 €**	**- 12 599 292,05 €**	**164,91 €**	**- 510,73 €**	**149,74 €**	**152,74 €**	**155,79 €**	**214,23 €**	**1 089 107,35 €**	**317 075,93 €**	**250 046,21 €**	**249 851,44 €**
CUMULATIVE CASH	**12 607 946,84 €**	**8 654,79 €**	**8 819,70 €**	**8 308,97 €**	**8 458,72 €**	**8 611,45 €**	**8 767,24 €**	**8 981,47 €**	**1 098 088,81 €**	**1 415 164,75 €**	**1 665 210,96 €**	**1 915 062,40 €**

Source: Author

Provisional Balance Sheet

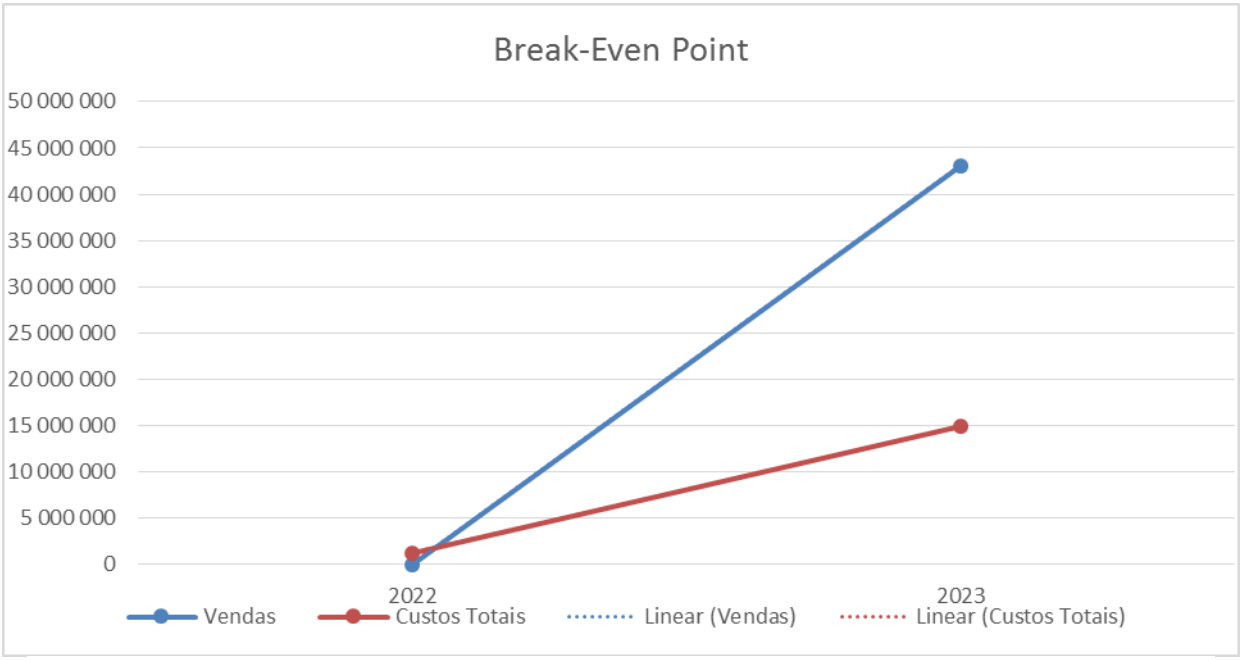
Table 20 - Balance Sheet, Commercialization

BALANÇO - A PREÇOS CORRENTES	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
ASSETS												
Non-current Assets												
Intangible Assets												
R&D Expenses	- €	- €	- €	- €	8 194 223,69 €	7 762 948,76 €	7 331 673,83 €	6 900 398,90 €	6 469 123,97 €	6 037 849,04 €	5 606 574,11 €	5 175 299,17 €
Patent	- €	- €	5 907 024,00 €	5 596 128,00 €	5 285 232,00 €	4 974 336,00 €	4 663 440,00 €	4 352 544,00 €	4 041 648,00 €	3 730 752,00 €	3 419 856,00 €	3 108 960,00 €
Sub-Total	**- €**	**- €**	**5 907 024,00 €**	**5 596 128,00 €**	**13 479 455,69 €**	**12 737 284,76 €**	**11 995 113,83 €**	**11 252 942,90 €**	**10 510 771,97 €**	**9 768 601,04 €**	**9 026 430,11 €**	**8 284 259,17 €**
Tangible Assets												
Transportation Equipment	18 750,00 €	31 550,00 €	18 950,00 €	6 350,00 €	20 216,01 €	34 097,67 €	41 518,30 €	42 348,66 €	43 195,64 €	44 059,55 €	44 940,74 €	53 580,17 €
Laboratory Equipment	57 904,72 €	48 258,43 €	38 612,15 €	28 965,87 €	19 319,59 €	9 673,30 €	27,02 €	66 682,44 €	55 645,34 €	44 608,25 €	33 571,15 €	22 534,06 €
Administrative Equipment	667,01 €	650,15 €	581,60 €	358,32 €	135,03 €	666,78 €	748,16 €	1 177,38 €	1 181,19 €	1 659,03 €	1 333,95 €	1 161,05 €
Sub-Total	**77 321,73 €**	**80 458,59 €**	**58 143,75 €**	**35 674,18 €**	**39 670,63 €**	**44 437,76 €**	**42 293,48 €**	**110 208,48 €**	**100 022,17 €**	**90 326,83 €**	**79 845,85 €**	**77 275,28 €**
Current Assets												
Inventory	- €	- €	- €	- €	- €	- €	- €	1 136 823,20 €	1 594 512,90 €	1 935 253,03 €	2 276 974,10 €	2 772 802,05 €
Account Receivables	- €	- €	- €	- €	- €	- €	- €	4 109 110,69 €	5 602 528,69 €	6 709 807,58 €	7 922 780,37 €	9 822 786,25 €
GOPE	3 755,74 €	2 511,97 €	119 458,17 €	1 945,50 €	165 547,56 €	2 550,75 €	2 602,59 €	- €	- €	- €	- €	- €
Financial applications	- €	11 099 996,43 €	3 422 388,29 €	2 129 360,41 €	- €	- €	- €	17 230 247,91 €	50 106 596,20 €	84 833 250,73 €	126 621 370,73 €	181 582 429,24 €
Cash and Equivalents	12 607 946,84 €	8 654,79 €	8 819,70 €	8 308,97 €	8 458,72 €	8 611,45 €	8 767,24 €	8 981,47 €	1 098 088,81 €	1 415 164,75 €	1 665 210,96 €	1 915 062,40 €
Sub-Total	**12 611 702,58 €**	**11 111 163,19 €**	**3 550 666,16 €**	**2 139 614,89 €**	**174 006,28 €**	**11 162,20 €**	**11 369,83 €**	**22 485 163,26 €**	**58 401 726,61 €**	**94 893 476,08 €**	**138 486 336,15 €**	**196 093 079,94 €**
TOTAL ASSETS	**12 689 024,31 €**	**11 191 621,77 €**	**9 515 833,91 €**	**7 771 417,07 €**	**13 693 132,60 €**	**12 792 884,72 €**	**12 048 777,14 €**	**33 848 314,64 €**	**69 012 520,74 €**	**104 752 403,95 €**	**147 592 612,11 €**	**204 454 614,39 €**
EQUITY												
Shared Capital	5 000 000,00 €	5 000 000,00 €	5 000 000,00 €	5 000 000,00 €	5 000 000,00 €	5 000 000,00 €	5 000 000,00 €	5 000 000,00 €	5 000 000,00 €	5 000 000,00 €	5 000 000,00 €	5 000 000,00 €
Other Equity Instruments	- €	- €	- €	- €	- €	30 000,00 €	1 530 000,00 €	- €	- €	- €	- €	- €
Reserves	- €	- €	- €	- €	- €	- €	- €	375 000,00 €	375 000,00 €	375 000,00 €	375 000,00 €	375 000,00 €
Reserves and Retained Earnings	- €	- 326 106,83 €	- 1 025 210,64 €	- 1 901 647,34 €	- 2 846 442,43 €	- 4 465 647,10 €	- 6 134 143,99 €	- 7 851 694,43 €	13 718 046,02 €	39 793 287,80 €	71 598 779,86 €	109 901 652,37 €
Retained Earnings	- 326 106,83 €	- 699 103,81 €	- 876 436,71 €	- 944 795,08 €	- 1 619 204,67 €	- 1 668 496,89 €	- 1 717 550,44 €	- €	21 569 740,45 €	26 075 241,78 €	31 805 492,06 €	38 302 872,51 €
Payout	- €	- €	- €	- €	- €	- €	- €	6 039 876,86 €	11 175 103,62 €	13 630 925,17 €	16 415 516,79 €	20 776 845,53 €
TOTAL EQUITY	**4 673 893,17 €**	**3 974 789,36 €**	**3 098 352,66 €**	**2 153 557,57 €**	**534 352,90 €**	**- 1 104 143,99 €**	**- 1 321 694,43 €**	**25 132 922,88 €**	**56 343 391,42 €**	**90 604 705,03 €**	**131 692 169,16 €**	**184 532 804,14 €**
LIABILITIES												
Long Run Liabilities												
Bank Loans	7 200 000,00 €	6 400 000,00 €	5 600 000,00 €	4 800 000,00 €	4 000 000,00 €	3 200 000,00 €	2 400 000,00 €	1 600 000,00 €	800 000,00 €	- €	- €	- €
Sub-Total	**7 200 000,00 €**	**6 400 000,00 €**	**5 600 000,00 €**	**4 800 000,00 €**	**4 000 000,00 €**	**3 200 000,00 €**	**2 400 000,00 €**	**1 600 000,00 €**	**800 000,00 €**	**- €**	**- €**	**- €**
Short Run Liabilities												
Account Payables	8 654,79 €	8 942,20 €	8 424,38 €	8 576,20 €	8 731,06 €	8 889,01 €	9 106,21 €	1 113 340,05 €	1 434 819,81 €	1 688 338,89 €	1 941 660,49 €	2 323 349,34 €
GOPE	6 476,34 €	7 890,21 €	9 056,88 €	9 283,30 €	9 515,38 €	9 753,27 €	11 772,54 €	61 747,41 €	81 857,54 €	97 128,97 €	109 871,36 €	129 317,08 €
Taxes on Profits	- €	- €	- €	- €	- €	- €	- €	5 140 304,30 €	9 552 451,97 €	11 562 231,06 €	13 848 911,10 €	17 469 143,83 €
Bank Loans												
Bank Loans in Euros	800 000,00 €	800 000,00 €	800 000,00 €	800 000,00 €	800 000,00 €	800 000,00 €	800 000,00 €	800 000,00 €	800 000,00 €	800 000,00 €	- €	- €
Short-Run Financing	- €	- €	- €	- €	8 340 533,26 €	9 878 386,44 €	10 149 592,81 €	- €	- €	- €	- €	- €
Sub-Total	**815 131,14 €**	**816 832,41 €**	**817 481,26 €**	**817 859,50 €**	**9 158 779,70 €**	**10 697 028,71 €**	**10 970 471,57 €**	**7 115 391,76 €**	**11 869 129,32 €**	**14 147 698,92 €**	**15 900 442,95 €**	**19 921 810,25 €**
TOTAL LIABILITIES	**8 015 131,14 €**	**7 216 832,41 €**	**6 417 481,26 €**	**5 617 859,50 €**	**13 158 779,70 €**	**13 897 028,71 €**	**13 370 471,57 €**	**8 715 391,76 €**	**12 669 129,32 €**	**14 147 698,92 €**	**15 900 442,95 €**	**19 921 810,25 €**
TOTAL EQUITY AND LIABILITES	**12 689 024,31 €**	**11 191 621,77 €**	**9 515 833,91 €**	**7 771 417,07 €**	**13 693 132,60 €**	**12 792 884,72 €**	**12 048 777,14 €**	**33 848 314,64 €**	**69 012 520,74 €**	**104 752 403,95 €**	**147 592 612,11 €**	**204 454 614,39 €**

Source: Author

Break-Even Point

Figure 11 - Break-Even Point, Commercialization



Source: Author

The Break-Even analysis allows the company which will commercialize the product to understand how much units of product needs to sell in order to cover the investments made. In this way, the company has to sell 179783 units of *Prophyl-ACT* to cover the total investment. With a unit selling price of 21.89€, the company has to make 393546.73€ in sales to achieve this situation.

Sensitivity Analysis

Sensitivity analysis is an important risk management tool because it allows to identify some risks behind a project and quantify them, in order to understand the real struggle of the risk considered and build the mitigation plan.

Given that the purchasing company is well established in the market, there are some risks intrinsic to the R&D phases that are minimized. In this way, it is important to emphasize the risk related to a negative variation on the sales and study its impact on the viability of the project.

Table 21 shows the impact of a variation on the quantity sold of *Prophyl-ACT* during the first five years of sales. This variation is considered to be less 20% in a pessimistic scenario and more 20% in an optimistic scenario. This numbers are assumed considering the

probability of the appearance of a competitor in the market, which can struggle the commercial success of the project.

Table 21 - Sensitivity Analysis for Quantity Sold, Commercialization

Scenarios	Actual	Pessimistic	Optimistic
Variable Cells			
Quantity Sold		-20%	20%
Results Cells			
NPV	96 815 006,12 €	66 099 114,89 €	127 530 897,49 €
IRR	47,02%	39,41%	53,05%
Payback	7,03	7,91	6,89
BEP			
€	3 935 461,73 €	3 981 540,57 €	4 016 466,27 €
Quantity	179 783	181 888	183 484

Source: Author

Other important variable that the company may have difficulties to control are the variable costs of manufacturing the drug. Therefore, if the variable costs increase the margin will decrease, considering that the selling price cannot increase. Thus, an analysis considering a variation of the unit margin helps to observe the impact on varying the variable costs of the company.

Table 22 - Sensitivity Analysis for Unit Margin, Commercialization

Scenarios	Actual	Pessimistic	Optimistic
Variable Cells			
Unit Margin	**55%**	**45%**	**65%**
Results Cells			
NPV	96 815 006,12 €	81 450 044,58 €	112 179 967,81 €
IRR	47,02%	43,47%	50,19%
Payback	7,03	7,22	6,94
BEP			
€	3 935 461,73 €	3 934 931,80 €	3 965 912,94 €
Quantity	179 783	199 742	164 697

Source: Author

In order to have a more detailed sensitivity analysis, it is important understand the impact of a combination of changes in the unit margin and in the quantity of *Prophyl-ACT* sold. In this fashion, *table 23* joints the two changes and gives the impact on the Net Present Value of the project.

Table 23 - Sensitivity Analysis for Quantity Sold and Unit Margin, Commercialization

	-20%	-10%	0%	10%	20%
45%	53 807 145,60 €	67 628 595,09 €	81 450 044,58 €	95 271 494,07 €	109 092 943,55 €
50%	59 925 066,39 €	74 511 255,98 €	89 097 445,56 €	103 683 635,15 €	118 269 824,74 €
55%	66 099 114,89 €	81 457 060,54 €	96 815 006,19 €	112 172 951,84 €	127 530 897,49 €
60%	72 217 035,68 €	88 339 721,43 €	104 462 407,18 €	120 585 092,93 €	136 707 778,67 €
65%	78 391 084,18 €	95 285 526,00 €	112 179 967,81 €	129 074 409,62 €	145 968 851,43 €

Source: Author

Thus, combining a negative variation of 20% on product sold with a 45% margin on the products, the company will obtain a Net Present Value of 53807145.60€. On the other side, if the company increase its margin to 65% and the sales of the product are 20% higher than the expected, the NPV of AMS will be 145968851.43€.

Ratios

In order to provide relevant and reliable information during the negotiations, and given that AMS does not have the confidential information about the pharmaceutical company that will buy the patent, the most important ratios to provide are those related with the sales performance. The following tables shows those indicators along the years of activity provided.

Table 25 - Economic Indicators, Commercialization

Economic Indicators	2023	2024	2025	2026	2027
Growth Rate of the Business		36%	20%	18%	24%
Operating Margin	69%	71%	71%	72%	73%
Rentabilidade Líquida das Vendas	53%	55%	56%	57%	57%

Source: Author

Table 24 - Financial Indicators

Financial Indicatiors	2023	2024	2025	2026	2027
Return On Investment (ROI)	77%	54%	43%	36%	33%
Return on Assets (ROA)	98%	68%	54%	46%	42%
Return on Equity (ROE)	104%	66%	50%	41%	37%

Source: Author

12. Risks of the project

The exercise performed in this business plan was made in order to forecast all the processes and activities that will be done and identify the needs of the project. This work was based in assumptions that are willing to be right. However, there are variables that cannot be identified and so, there are some risks behind this business plan related with the external environment.

First of all, this project needs a huge amount of investment to start the phases of R&D. The company is very exposed to external investors and the fund raising process may be planned accurately. However, given that there is a considerably high probability of failing in crucial phases, investors may prefer to invest in other projects with lower risks. In this way, the company shall try to give a good compensation to those investors that fund the beginning of the company, giving an important part of the company's shares to them. Additionally, the out-licensing after the Clinical Trials Phase I helps to divide the risk between the companies and the investors have their return earlier.

Advancing for further phases, considering that the initial investment is raised, the company will proceed to expensive and risky legal phases that are mandatory in the development of drugs. In this way, if the company fails the Proof of Concept or the Clinical Trials Phase I/II-A, this business plan does not make sense anymore, given that the patent will not be sold to a pharmaceutical company. However, instead of advancing to a pharmaceutical product, the company may follow to develop and launch a food supplement to the nutraceutical market. This is only possible due to the usage of already approved compounds on the manufacturing of the product.

Finally, other important risk that the company may face is the phase of negotiating the patent sale with a big pharmaceutical company. Since the company does not have enough funds and expertise to develop an efficient supply chain to launch the product, this will put the company in a weaker situation in negotiations, which can cause a price decrease of the patent, affecting the profitability of the company.

13. Conclusion

After performing all the analysis included in this business plan, there are some important conclusions to highlight.

First of all, one problem identified was the blockbuster business model that characterizes the pharmaceutical industry. This business plan is an additional example of an alternative to the blockbuster business model, by dividing the R&D phases to some specialized SME and the commercial phase to big pharmaceutical countries. With this, the risks are divided by those two types of companies and both companies would save funds. This business model should be a realistic alternative to the blockbuster business model.

Secondly, focusing on AntiMalarial Solutions, the vast experience of its members on the research in malaria constitutes a unique resource of the company to perform R&D in this specific disease. This means that the company will be able to develop more therapeutics to offer to the pharmaceutical industry. As follows, the strategy of the company is adequate given that will focus on the core competencies of the human resources of the company and it will avoid the risks associated with other activities which are not known by the company's members.

Considering the sale of the patent, the most important asset of AMS, the company will receive a value that is a fair value for it. By covering the costs that the company incurred during the first three years, it will allow to give an adequate compensation to shareholders and to save some money to advance to R&D directed to other therapeutics.

Finally, the financials of the company indicate that this project is worth of investment, due to a NPV of 490267.18€, an Internal Rate of Return of 16.43% and a Payback period of 3 years, 10 months and 17 days.

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Appendix

Appendix I – Internal, External and Competitive Analysis

Table 26 - SWOT Analysis

Internal Factors	Strengths	Easy communication of the solution delivered Product Performance Team's Knowledge about malaria Use of already approved compounds Simplicity of the organization's structure Tasks well defined within the company
	Weaknesses	Legal procedures require high investments Lack of network to establish the needed agreements and partnerships Lack of knowledge of the total costs of the business High funding needs due to expensive R&D
External Factors	Opportunities	Market Size Market allies and partners, in order to deliver the product to the maximum of travellers Existing and well-established distribution channels High number of travellers that do not take prophylactic medicines to avoid malaria Important lack on prophylactic solutions to avoid malaria Possibility to out-license the drug to well established pharmaceutical companies
		Possibility of using the technology in different applications Adverse effects of existing prophylactic medicines
	Threats	Low price of direct competition Worldwide effort to develop alternative products to treat malaria High possibility of new entrants with better solutions

Source: Author

Table 27 - Porter's 5 Forces

Porter's 5 Forces Model								
			1	2	3	4	5	
Bargaining Power of Buyers								
Number of clients		High	x					Low
Client's cost of changing the medicine		High					x	Low
Severity Side effects of the medicine		Low					x	High
Price of the medicine		Low				x		High
Information availability to clients		Low			x			High
Willingness to take the risk							x	
Number of travels per client		Low			x			High
	Global Force Value	3,71						
Bargaining Power of Suppliers								
Number of Suppliers available		High			x			Low
Price combination between suppliers		Low					x	High
Size of our company		Big					x	Small
	Global Force Value	4,333333333						
Threat of Substitutes								
Efficacy of Substitute products		Low	x					High
Number of products		Low		x				High
	Global Force Value	1,5						
Threat of New Entrants								
Incentives to R&D in the area		Low					x	High
Legal requirements		High		x				Low
Capital Required to enter the market		High	x					Low
Time-to-market period		High		x				Low
Venture Capital interested to invest		Low				x		High
Clinical Trials performance		High		x				Low
	Global Force Value	2,67						
Competitive Rivalry								
Severity of Side effects		High		x				Low
Parasite resistance		High		x				Low
Price of competitors' products		High				x		Low
Efficacy of the direct competitors		Low		x				High
	Global Force Value	2,5						

Source: Author

Table 28 - TOWS Analysis

		External Factors	
		Opportunities	Threats
Internal Factors	Strengths	**SO Strategies:**	**ST Strategies**
		Communicate the product to attract travellers that buy other prophylactics; Communicate the product to attract travellers that do not buy prophylactics; Use the team's knowledge to apply to R&D funds and get financial assets to accomplish the plan Use the team's knowledge to develop other solutions Provide a simple communication to attract possible buyers to the patent	Development of a high performance product to facilitate the approvals on legal procedures and clinical trials; Maintain a simple structure to better cope with the uncertainty and keep the costs under control Use of this technology in other ways, in the case of not getting the approval on clinical trials; Out-license, as a way to avoid huge investments on further clinical trials and commercialization Product performance and easy communication to raise funds to Clinical Trials Phase I/II-A.
		WO Strategies	**WT Strategies**
	Weaknesses	Use the market size and market growth to increase the selling price of the patent Explore the lack of solutions to develop an important pipeline of investigation, reducing the dependence of a single product	Reduce the time to and avoid being overpassed by new competitors in the market Getting approval on clinical trials in order to avoid more investments in R&D and legal procedures Seize the worldwide effort to develop new antimalarial medicines to attract investment and funding to reduce the expensive R&D activities

Source: Author

Appendix 2 – Sales Forecast and Financial Planning - AMS

Table 29 - Project's Assumptions

Assumptions of the Project			
Interest Rate Treasury bills 10 years	2,84%	Average Invetory Period	30
Short-Run Financing Interest Rate	3,00%	Account Recievables Period	30
Short-Run Financial Applications Interest Rate	1,50%	Account Payables Period	30
Average Income Taxes	14,50%	Account Recievables/Payables VAT	30
Social Security Rate (Employees)	11,00%	Account Payables Period (Social Security)	30
Social Security Rate (Firms)	23,75%	Account Payables Period (Employees Income Taxes	30
Workers Accidents Insurance	1,00%	Net Working Capital Period	30
Food Allowance (4,27/day)	93,94 €		
Balance Local State Tax (Derrama Estadual IRC	1,50%		
Average Tax Rate	19,00%		
Taxes on Profits	20,50%		
Payout	50,00%		
VAT undertaken to State (IVA Liquidado)	23,00%		
VAT Payed Tax (IVA Dedutível)	23,00%		
EUR/USD Exchange Rate	$ 1,08		

Source: Author

Table 30 - Personnel Costs, AMS

Personnel Costs - Current Prices		2016	2017	2018	2019
		0	1	2	3
Accumulated Factor of Wages Increase		**1,000**	**1,020**	**1,046**	**1,072**
Staff					
CEO		1	1	1	1
CIO		1	1	1	1
Lab Technician		2	2	2	2
Crinical Trials Specialist			1	1	1
Marketing Manager					
Administrative		1	1	1	1
Total Staff		**5**	**6**	**6**	**6**
Average Monthly Salary					
CEO	€ 3 850,43	€ 3 850,43	€ 3 927,44	€ 4 025,62	€ 4 126,27
CIO	€ 3 390,48	€ 3 390,48	€ 3 458,29	€ 3 544,75	€ 3 633,37
Lab Technician	€ 1 600,43	€ 1 600,43	€ 1 632,44	€ 1 673,25	€ 1 715,08
Crinical Trials Specialist	€ 2 221,86	€ 2 221,86	€ 2 266,30	€ 2 322,95	€ 2 381,03
Marketing Manager	€ 2 714,72	€ 2 714,72	€ 2 769,01	€ 2 838,24	€ 2 909,20
Sales Manager	€ 3 707,58	€ 3 707,58	€ 3 781,73	€ 3 876,27	€ 3 973,18
Sales Representative	€ 3 564,72	€ 3 564,72	€ 3 636,01	€ 3 726,91	€ 3 820,09
Quality Control Manager	€ 1 636,15	€ 1 636,15	€ 1 668,87	€ 1 710,59	€ 1 753,36
Administrative	€ 986,15	€ 986,15	€ 1 005,87	€ 1 031,02	€ 1 056,80
Average Annual Salary					
CEO		€ 53 906,02	€ 54 984,14	€ 56 358,74	€ 57 767,71
CIO		€ 47 466,72	€ 48 416,05	€ 49 626,46	€ 50 867,12
Lab Technician		€ 44 812,04	€ 45 708,28	€ 46 850,99	€ 48 022,26
Crinical Trials Specialist		€ -	€ 31 728,16	€ 32 521,36	€ 33 334,40
Marketing Manager		€ -	€ -	€ -	€ -
Administrative		€ 13 806,10	€ 14 082,22	€ 14 434,28	€ 14 795,13
Total costs with wages		**€ 159 990,88**	**€ 194 918,86**	**€ 199 791,83**	**€ 204 786,63**
Variable Salaries (on Patent Sale)	2%				125 963,94 €
Total Personel Costs With Variable Salary		**€ 159 990,88**	**€ 194 918,86**	**€ 199 791,83**	**€ 330 750,57**
Other Personel Costs					
Food Allawance	€ 93,94	€ 5 166,70	€ 6 200,04	€ 6 200,04	€ 6 200,04
Social Security Discounts	23,75%	€ 37 997,83	€ 46 293,23	€ 47 450,56	€ 78 553,26
Workers Accident Insurance	1,00%	€ 1 599,91	€ 1 949,19	€ 1 997,92	€ 3 307,51
Total Personel Costs		**€ 204 755,32**	**€ 249 361,32**	**€ 255 440,35**	**€ 418 811,38**

Source: Author

Table 32 - Government and Other Public Entities, AMS

GOVERNMENT AND OTHER PUBLIC ENTITIES - VAT, SOCIAL SECURITY, INCOME TAXES - CURRENT PRICES					
VALUE ADDED TAX		**2016**	**2017**	**2018**	**2019**
Total Revenues (Patent)					6 298 197,24 €
RECEIVED VAT	**23,00%**	**- €**	**- €**	**- €**	**1 448 585,37 €**
Total Purchases		91 425,00 €	92 727,80 €	86 091,80 €	87 613,63 €
Investment in Assets		393 373,23 €	142 258,77 €	2 269 397,59 €	- €
PAYED VAT	**23,00%**	**111 503,59 €**	**54 046,91 €**	**541 762,56 €**	**20 151,14 €**
IVA TO RECEIVE/PAY		**- 111 503,59 €**	**- 54 046,91 €**	**- 541 762,56 €**	**1 428 434,23 €**
VAT TO Receive	**30**	**- 9 164,68 €**	**- 4 442,21 €**	**- 44 528,43 €**	**117 405,55 €**
SOCIAL SECURITY AND INCOME TAXES		**2016**	**2017**	**2018**	**2019**
Wages (14 months)		159 990,88 €	194 918,86 €	199 791,83 €	330 750,57 €
Social Security (Company)	**23,75%**	37 997,83 €	46 293,23 €	47 450,56 €	78 553,26 €
Social Security (Workers)	**11,00%**	17 599,00 €	21 441,07 €	21 977,10 €	36 382,56 €
SOCIAL SECURITY	**30**	**4 569,60 €**	**5 567,20 €**	**5 706,38 €**	**9 446,78 €**
Personnel Income Tax (Retention)	**14,50%**	23 198,68 €	28 263,23 €	28 969,82 €	47 958,83 €
INCOME TAX	**30**	**1 906,74 €**	**2 323,01 €**	**2 381,08 €**	**3 941,82 €**
SOCIAL SECURITY AND INCOME TAXES		**6 476,34 €**	**7 890,21 €**	**8 087,46 €**	**13 388,60 €**

Source: Author

Table 31 - Investments, AMS

INVESTMENT IN FIXED CAPITAL - REINVESTMENTS MADE AFTER THE LAST YEAR AMORTIZATION - CURRENT PRICES								
					2016	**2017**	**2018**	**2019**
	Aquisition Cost		**Useful Life**	**Dep. Tax**	**0**	**1**	**2**	**3**
Accumulated Inflation Factor					**1,000**	**1,016**	**1,036**	**1,057**
FIXED TANGIBLE ASSETS								
Transportation Equipments								
Vehicle	€	25 000,00	4	25%	25 000,00 €	- €	- €	- €
Sub-total	**€**	**25 000,00**			**25 000,00 €**	**- €**	**- €**	**- €**
Lab Equipmens								
Flow Cytometer	€	45 000,00	7	14%	45 000,00 €	- €	- €	- €
Incubator	€	13 000,00	7	14%	13 000,00 €	- €	- €	- €
Fridge	€	2 091,00	7	14%	2 091,00 €	- €	- €	- €
Pipettes	€	5 000,00	7	14%	5 000,00 €	- €	- €	- €
Freezer	€	2 460,00	7	14%	2 460,00 €	- €	- €	- €
Sub-total	**€**	**67 551,00**			**67 551,00 €**	**- €**	**- €**	**- €**
Administrative Equipment								
Printing Machine	€	529,00	5	20%	529,00 €	- €	- €	- €
Mobile Phone 1 (CEO)	€	146,26	5	20%	146,26 €	- €	- €	- €
Mobile Phone 2 (Clinical Trials Specialist)	€	146,26	5	20%		148,44 €	- €	- €
Phone 1	€	23,97	5	20%	23,97 €	- €	- €	- €
Phone 2	€	23,97	5	20%		24,33 €	- €	- €
Furniture	€	123,00	8	13%	123,00 €	- €	- €	- €
Sub-total	**€**	**992,46**			**822,23 €**	**172,77 €**	**- €**	**- €**
FIXED TANGIBLE ASSETS	**€**	**93 543,46**			**93 373,23 €**	**172,77 €**	**- €**	**- €**
INTAGIBLE ASSETS								
R&D Expenses								
R&D for other products	€	80 000,00	3	33%		81 192,00 €	- €	- €
Proof of Concept	€	300 000,00	20	5%	300 000,00 €	- €	- €	- €
Clinical Trials Phase I/IIA	€	2 200 000,00	20	5%			2 269 397,59 €	- €
Sub-total	**€**	**2 500 000,00**			**300 000,00 €**	**81 192,00 €**	**2 269 397,59 €**	**- €**
Industrial Property								
Patent	€	60 000,00	20	5%		60 894,00 €	- €	- €
Sub-total	**€**	**60 000,00**			**- €**	**60 894,00 €**	**- €**	**- €**
INTANGIBLE ASSETS	**€**	**2 560 000,00**			**300 000,00 €**	**142 086,00 €**	**2 269 397,59 €**	**- €**
TOTAL ASSETS	**€**	**2 653 543,46**			**393 373,23 €**	**142 258,77 €**	**2 269 397,59 €**	**- €**

Source: Author

Table 34 - Depreciations and Amortizations, AMS

AMORTIZATIONS AND DEPRECIATIONS OF FIXED CAPITAL - REINVESTMENTS MADE AFTER THE LAST YEAR AMORTIZATION - CURRENT PRICES								
					2016	2017	2018	2019
	Aquisition Cost	Useful Life	Dep. Tax		0	1	2	3
FIXED TANGIBLE ASSETS								
Transportation Equipments								
Vehicle 1	€ 25 000,00	4	25%		€ 6 250,00	€ 6 250,00	€ 6 250,00	€ 6 250,00
Sub-total	**€ 25 000,00**				**€ 6 250,00**	**€ 6 250,00**	**€ 6 250,00**	**€ 6 250,00**
Lab Equipmens								
Flow Cytometer	€ 45 000,00	7	14,29%		€ 6 426,00	€ 6 426,00	€ 6 426,00	€ 6 426,00
Incubator	€ 13 000,00	7	14,29%		€ 1 856,40	€ 1 856,40	€ 1 856,40	€ 1 856,40
Fridge	€ 2 091,00	7	14,29%		€ 298,59	€ 298,59	€ 298,59	€ 298,59
Pipettes	€ 5 000,00	7	14,29%		€ 714,00	€ 714,00	€ 714,00	€ 714,00
Freezer	€ 2 460,00	7	14,29%		€ 351,29	€ 351,29	€ 351,29	€ 351,29
Sub-total	**€ 67 551,00**				**€ 9 646,28**	**€ 9 646,28**	**€ 9 646,28**	**€ 9 646,28**
Administrative Equipment								
Printing Machine	€ 529,00	5	20%		€ 105,80	€ 105,80	€ 105,80	€ 105,80
Mobile Phone 1 (CEO)	€ 146,26	5	20%		€ 29,25	€ 29,25	€ 29,25	€ 29,25
Mobile Phone 2 (Clinical Trials Specialist)	€ 146,26	5	20%			€ 29,69	€ 29,69	€ 29,69
Phone 1	€ 23,97	5	20%		€ 4,79	€ 4,79	€ 4,79	€ 4,79
Phone 2	€ 23,97	5	20%			€ 4,87	€ 4,87	€ 4,87
Furniture	€ 123,00	8	13%		€ 15,38	€ 15,38	€ 15,38	€ 15,38
Sub-total	**€ 992,46**				**€ 155,22**	**€ 189,77**	**€ 189,77**	**€ 189,77**
TOTAL DEP. FIXED TANGIBLE ASSETS	**€ 93 543,46**				**€ 16 051,50**	**€ 16 086,06**	**€ 16 086,06**	**€ 16 086,06**
INTAGIBLE ASSETS								
R&D Expenses								
R&D for other products	€ 80 000,00	3	33%			€ 27 061,29	€ 27 061,29	€ 27 061,29
Proof of Concept	€ 300 000,00	20	5%		€ 15 000,00	€ 15 000,00	€ 15 000,00	€ 15 000,00
Clinical Trials Phase I/IIA	€ 2 200 000,00	20	5%				€ 113 469,88	€ 113 469,88
Sub-total	**€ 80 000,00**				**€ 15 000,00**	**€ 42 061,29**	**€ 155 531,17**	**€ 155 531,17**
Industrial Property								
Patent	€ 60 000,00	20	5%			€ 3 044,70	€ 3 044,70	€ 3 044,70
Sub-total	**€ 60 000,00**				**€ -**	**€ 3 044,70**	**€ 3 044,70**	**€ 3 044,70**
TOTAL DEP. INTANGIBLE ASSETS	**€ 140 000,00**				**€ 15 000,00**	**€ 45 105,99**	**€ 158 575,87**	**€ 158 575,87**
TOTAL DEP. ASSETS	**€ 233 543,46**				**€ 31 051,50**	**€ 61 192,05**	**€ 174 661,93**	**€ 174 661,93**

Source: Author

Appendix 3 – Sales Forecast and Financial Planning – Commercialization

Table 33 - Travellers for malaria endemic regions

	Travellers to those regions (Million)	% Malaria regions	Travelers to malaria endemic Regions in 2014 (Million)
Sub-Saharan Africa	34,2	100%	34,20
Central America	9,6	100%	9,60
Caribean	22,2	10%	2,22
South America	29,1	5%	1,46
Asia	251,2	10,8%	27,13
Total			**74,60**

Source: Author

Table 36 - Market entry per year

	Number of cases (2010)***	% of number of cases	Travelers to malaria endemic regions	Market entry year
Austria	48	0,49%	320645	-
Belgium	166	1,69%	1108898	2027
Finland	33	0,34%	220443	-
France	2439	24,87%	16292797	2024
Germany	615	6,27%	4108270	2025
Greece	45	0,46%	300605	-
Ireland	82	0,84%	547769	-
Italy	662	6,75%	4422235	2026
Netherlands	247	2,52%	1649988	2027
Portugal	50	0,51%	334005	2023
Spain	351	3,58%	2344719	2024
Sweden	115	1,17%	768213	-
United Kingdom	1761	17,95%	11763680	2025
Other EU Countries	108	1,10%	721452	-
EU Total	6722	68,54%	44903725	
USA	1688	17,21%	11276032	-
China	1398	14,25%	9338799	-
TOTAL	**9808**	**1**	**65518550**	

Source: Author

Table 35 - Quantity sold per country

	Number of Travellers to endemic malaria regions (2023)	2023	2024	2025	2026	2027
Portugal	509389	21394	22463	24765	28668	34846
Spain	3575972	150190	157699	173863	201268	244642
France	24848474	1043635	1095816	1208137	1398569	1699969
United Kingdom	17941022	753522	791198	872295	1009790	1227406
Germany	6265599		271839	299702	346942	421710
Italy	6744435		292614	322606	373456	453938
Belgium	1691195			75795	87742	106650
Netherlands	2516424			112780	130556	158691
Total	**64092510**	**1968741**	**2631629**	**3089943**	**3576991**	**4347852**

Source: Author

Table 39 - Market penetration rate

	Sovaldi Scenario	Harvoni Scenario
	Units Sold	Units Sold
2014	170000	250000
Total Market	10000000	10000000
Aggregated Penetration Rate	4,20%	

Source: Author

Table 38 - Price of Prophyl-ACT

	Portugal	Spain	France	UK	Germany	Italy	Belgium	Netherlands
Compounds Price	€ 0,78	€ 0,78	€ 0,78	€ 0,78	€ 0,78	€ 0,78	€ 0,78	€ 0,78
Blister & Packaging	€ 5,82	€ 5,82	€ 5,82	€ 5,82	€ 5,82	€ 5,82	€ 5,82	€ 5,82
Manufacturers Cost	€ 3,25	€ 3,25	€ 3,25	€ 3,25	€ 3,25	€ 3,25	€ 3,25	€ 3,25
Unit Manuf. Cost	€ 9,85	€ 9,85	€ 9,85	€ 9,85	€ 9,85	€ 9,85	€ 9,85	€ 9,85
Company's Margin (%)	55,00%	55,00%	55,00%	55,00%	55,00%	55,00%	55,00%	55,00%
Company's Margin (€)	€ 12,04	€ 12,04	€ 12,04	€ 12,04	€ 12,04	€ 12,04	€ 12,04	€ 12,04
Price *Prophyl-ACT*	€ 21,89	€ 21,89	€ 21,89	€ 21,89	€ 21,89	€ 21,89	€ 21,89	€ 21,89
Wholesalers and Dist. Margin	10,00%	3,50%	6,20%	12,00%	5,05%	6,65%	8,50%	18,50%
Pharmacy Margin	21,90%	22,00%	22,00%	22,00%	24,00%	22,00%	22,00%	22,00%
Pharmacy Fee	€ 0,45	€ 0,45	€ 0,45	€ 0,45	€ 0,45	€ 0,45	€ 0,45	€ 0,45
PVP(s/VAT)	€ 28,87	€ 27,47	€ 28,06	€ 29,33	€ 28,25	€ 28,16	€ 28,57	€ 30,76
Inf Tax	0,40%	0,40%	0,40%	0,40%	0,40%	0,40%	0,40%	0,40%
VAT	6%	10%	10%	20%	19%	10%	20%	6%
End User Price (c/VAT)	**€ 30,73**	**€ 30,34**	**€ 30,99**	**€ 35,34**	**€ 33,75**	**€ 31,10**	**€ 34,42**	**€ 32,73**

Source: Author

Table 37 - Manufacturing Cost of Prophyl-ACT

	€
Compounds Price	€ 0,78
Blister & Packaging	€ 5,82
Manufacturers Cost	€ 3,25
Unit Manuf Cost	€ 9,85

Source: Author

Table 40 - Personnel costs, Commercialization

Personnel Costs - Current Prices													
		2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
		0	1	2	3	4	5	6	7	8	9	10	11
Accumulated Factor of Wages Increase		**1,000**	**1,020**	**1,046**	**1,072**	**1,098**	**1,126**	**1,154**	**1,189**	**1,224**	**1,261**	**1,299**	**1,338**
Staff													
CEO		1	1	1	1	1	1	1	1	1	1	1	1
CIO		1	1	1	1	1	1	1	1	1	1	1	1
Lab Technician		2	2	2	2	2	2	2	2	2	3	3	3
Crinical Trials Specialist			1	1	1	1	1	1	1	1	1	1	1
Marketing Manager								1	1	1	1	1	1
Sales Manager									1	1	1	1	1
Sales Representative									3	5	6	6	6
Quality Control Manager				1	1	1	1	1	1	1	1	1	1
Administrative		1	1	1	1	1	1	1	1	1	1	1	1
Total Staff		**5**	**6**	**7**	**7**	**7**	**7**	**8**	**12**	**14**	**16**	**16**	**16**
Average Monthly Salary													
CEO	3 850,43 €	3 850,43 €	3 927,44 €	4 025,62 €	4 126,27 €	4 229,42 €	4 335,16 €	4 443,54 €	4 576,84 €	4 714,15 €	4 855,57 €	5 001,24 €	5 151,28 €
CIO	3 390,48 €	3 390,48 €	3 458,29 €	3 544,75 €	3 633,37 €	3 724,20 €	3 817,30 €	3 912,74 €	4 030,12 €	4 151,02 €	4 275,55 €	4 403,82 €	4 535,93 €
Lab Technician	1 600,43 €	1 600,43 €	1 632,44 €	1 673,25 €	1 715,08 €	1 757,96 €	1 801,91 €	1 846,95 €	1 902,36 €	1 959,43 €	2 018,22 €	2 078,76 €	2 141,13 €
Crinical Trials Specialist	2 221,86 €	2 221,86 €	2 266,30 €	2 322,95 €	2 381,03 €	2 440,55 €	2 501,57 €	2 564,11 €	2 641,03 €	2 720,26 €	2 801,87 €	2 885,93 €	2 972,50 €
Marketing Manager	2 714,72 €	2 714,72 €	2 769,01 €	2 838,24 €	2 909,20 €	2 981,93 €	3 056,47 €	3 132,89 €	3 226,87 €	3 323,68 €	3 423,39 €	3 526,09 €	3 631,87 €
Sales Manager	3 707,58 €	3 707,58 €	3 781,73 €	3 876,27 €	3 973,18 €	4 072,51 €	4 174,32 €	4 278,68 €	4 407,04 €	4 539,25 €	4 675,43 €	4 815,69 €	4 960,17 €
Sales Representative	3 564,72 €	3 564,72 €	3 636,01 €	3 726,91 €	3 820,09 €	3 915,59 €	4 013,48 €	4 113,82 €	4 237,23 €	4 364,35 €	4 495,28 €	4 630,14 €	4 769,04 €
Quality Control Manager	1 636,15 €	1 636,15 €	1 668,87 €	1 710,59 €	1 753,36 €	1 797,19 €	1 842,12 €	1 888,18 €	1 944,82 €	2 003,17 €	2 063,26 €	2 125,16 €	2 188,91 €
Administrative	986,15 €	986,15 €	1 005,87 €	1 031,02 €	1 056,80 €	1 083,22 €	1 110,30 €	1 138,05 €	1 172,19 €	1 207,36 €	1 243,58 €	1 280,89 €	1 319,32 €
Average Annual Salary													
CEO		53 906,02 €	54 984,14 €	56 358,74 €	57 767,71 €	59 211,91 €	60 692,20 €	62 209,51 €	64 075,79 €	65 998,07 €	67 978,01 €	70 017,35 €	72 117,87 €
CIO		47 466,72 €	48 416,05 €	49 626,46 €	50 867,12 €	52 138,80 €	53 442,26 €	54 778,32 €	56 421,67 €	58 114,32 €	59 857,75 €	61 653,48 €	63 503,09 €
Lab Technician		44 812,04 €	45 708,28 €	46 850,99 €	48 022,26 €	49 222,82 €	50 453,39 €	51 714,72 €	53 266,17 €	54 864,15 €	84 765,11 €	87 308,07 €	89 927,31 €
Crinical Trials Specialist		- €	31 728,16 €	32 521,36 €	33 334,40 €	34 167,76 €	35 021,95 €	35 897,50 €	36 974,43 €	38 083,66 €	39 226,17 €	40 402,95 €	41 615,04 €
Marketing Manager		- €	- €	- €	- €	- €	- €	43 860,40 €	45 176,21 €	46 531,50 €	47 927,44 €	49 365,27 €	50 846,22 €
Sales Manager		- €	- €	- €	- €	- €	- €	- €	61 698,60 €	63 549,56 €	65 456,04 €	67 419,72 €	69 442,31 €
Sales Representative		- €	- €	- €	- €	- €	- €	- €	177 963,70 €	305 504,36 €	377 603,39 €	388 931,49 €	400 599,43 €
Quality Control Manager		- €	- €	23 948,33 €	24 547,04 €	25 160,71 €	25 789,73 €	26 434,47 €	27 227,51 €	28 044,33 €	28 885,66 €	29 752,23 €	30 644,80 €
Administrative		13 806,10 €	14 082,22 €	14 434,28 €	14 795,13 €	15 165,01 €	15 544,14 €	15 932,74 €	16 410,72 €	16 903,05 €	17 410,14 €	17 932,44 €	18 470,41 €
Total costs with wages		**159 990,88 €**	**194 918,86 €**	**223 740,16 €**	**229 333,66 €**	**235 067,00 €**	**240 943,68 €**	**290 827,67 €**	**539 214,80 €**	**677 592,99 €**	**789 109,71 €**	**812 783,00 €**	**837 166,49 €**
Variable Salaries (on Sales)	2%	- €	- €	- €	- €	- €	- €	- €	986 186,56 €	1 344 606,89 €	1 610 353,82 €	1 901 467,29 €	2 357 468,70 €
Total Personel Costs With Variable Salary		**159 990,88 €**	**194 918,86 €**	**223 740,16 €**	**229 333,66 €**	**235 067,00 €**	**240 943,68 €**	**290 827,67 €**	**1 525 401,36 €**	**2 022 199,87 €**	**2 399 463,53 €**	**2 714 250,29 €**	**3 194 635,19 €**
Other Personel Costs													
Food Allawance	93,94 €	5 166,70 €	6 200,04 €	7 233,38 €	7 233,38 €	7 233,38 €	7 233,38 €	8 266,72 €	12 400,08 €	14 466,76 €	16 533,44 €	16 533,44 €	16 533,44 €
Social Security Discounts	23,75%	37 997,83 €	46 293,23 €	53 138,29 €	54 466,74 €	55 828,41 €	57 224,12 €	69 071,57 €	362 282,82 €	480 272,47 €	569 872,59 €	644 634,44 €	758 725,86 €
Workers Accident Insurance	1,00%	1 599,91 €	1 949,19 €	2 237,40 €	2 293,34 €	2 350,67 €	2 409,44 €	2 908,28 €	15 254,01 €	20 222,00 €	23 994,64 €	27 142,50 €	31 946,35 €
Total Personel Costs		**204 755,32 €**	**249 361,32 €**	**286 349,23 €**	**293 327,12 €**	**300 479,47 €**	**307 810,62 €**	**371 074,24 €**	**1 915 338,28 €**	**2 537 161,10 €**	**3 009 864,20 €**	**3 402 560,68 €**	**4 001 840,84 €**

Source: Author

Table 41 - Government and other public entities, Commercialization

GOVERNMENT AND OTHER PUBLIC ENTITIES - VAT, SOCIAL SECURITY, INCOME TAXES - CURRENT PRICES													
VALUE ADDED TAX		**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**
Total Revenues (Patent)		- €	- €	- €	- €	- €	- €	- €	49 309 328,22 €	67 230 344,31 €	80 517 690,91 €	95 073 364,41 €	117 873 434,95 €
RECEIVED VAT	**13,00%**	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**	**6 410 212,67 €**	**8 739 944,76 €**	**10 467 299,82 €**	**12 359 537,37 €**	**15 323 546,54 €**
Total Purchases		105 300,00 €	107 306,40 €	101 092,53 €	102 914,38 €	104 772,67 €	106 668,12 €	109 274,53 €	13 360 080,56 €	17 217 837,75 €	20 260 066,70 €	23 299 925,89 €	27 880 192,11 €
Investment in Assets		93 373,23 €	25 572,95 €	6 218 071,57 €	- €	8 652 453,31 €	28 262,76 €	28 398,67 €	106 731,84 €	29 661,55 €	30 766,62 €	30 562,05 €	31 324,74 €
PAYED VAT	**23,00%**	**45 694,84 €**	**30 562,25 €**	**1 453 407,74 €**	**23 670,31 €**	**2 014 161,97 €**	**31 034,10 €**	**31 664,84 €**	**3 097 366,85 €**	**3 966 924,84 €**	**4 666 891,66 €**	**5 366 012,23 €**	**6 419 648,88 €**
IVA TO RECEIVE/PAY		**- 45 694,84 €**	**- 30 562,25 €**	**- 1 453 407,74 €**	**- 23 670,31 €**	**- 2 014 161,97 €**	**- 31 034,10 €**	**- 31 664,84 €**	**3 312 845,82 €**	**4 773 019,92 €**	**5 800 408,15 €**	**6 993 525,15 €**	**8 903 897,67 €**
VAT TO Receive	**30**	**- 3 755,74 €**	**- 2 511,97 €**	**- 119 458,17 €**	**- 1 945,50 €**	**- 165 547,56 €**	**- 2 550,75 €**	**- 2 602,59 €**	**272 288,70 €**	**392 303,01 €**	**476 745,88 €**	**574 810,29 €**	**731 827,21 €**
SOCIAL SECURITY AND INCOME TAXES		**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**
Wages (14 months)		159 990,88 €	194 918,86 €	223 740,16 €	229 333,66 €	235 067,00 €	240 943,68 €	290 827,67 €	1 525 401,36 €	2 022 199,87 €	2 399 463,53 €	2 714 250,29 €	3 194 635,19 €
Social Security (Company)	**23,75%**	37 997,83 €	46 293,23 €	53 138,29 €	54 466,74 €	55 828,41 €	57 224,12 €	69 071,57 €	362 282,82 €	480 272,47 €	569 872,59 €	644 634,44 €	758 725,86 €
Social Security (Workers)	**11,00%**	17 599,00 €	21 441,07 €	24 611,42 €	25 226,70 €	25 857,37 €	26 503,80 €	31 991,04 €	167 794,15 €	222 441,99 €	263 940,99 €	298 567,53 €	351 409,87 €
SOCIAL SECURITY	**30**	**4 569,60 €**	**5 567,20 €**	**6 390,39 €**	**6 550,15 €**	**6 713,90 €**	**6 881,75 €**	**8 306,52 €**	**43 567,97 €**	**57 757,35 €**	**68 532,62 €**	**77 523,45 €**	**91 244,03 €**
Personnel Income Tax (Retention)	**14,50%**	23 198,68 €	28 263,23 €	32 442,32 €	33 253,38 €	34 084,72 €	34 936,83 €	42 170,01 €	221 183,20 €	293 218,98 €	347 922,21 €	393 566,29 €	463 222,10 €
INCOME TAX	**30**	**1 906,74 €**	**2 323,01 €**	**2 666,49 €**	**2 733,15 €**	**2 801,48 €**	**2 871,52 €**	**3 466,03 €**	**18 179,44 €**	**24 100,19 €**	**28 596,35 €**	**32 347,91 €**	**38 073,05 €**
SOCIAL SECURITY AND INCOME TAXES		**6 476,34 €**	**7 890,21 €**	**9 056,88 €**	**9 283,30 €**	**9 515,38 €**	**9 753,27 €**	**11 772,54 €**	**61 747,41 €**	**81 857,54 €**	**97 128,97 €**	**109 871,36 €**	**129 317,08 €**

Source: Author

Table 42 - Investment, Commercialization

INVESTMENT IN FIXED CAPITAL - REINVESTMENTS MADE AFTER THE LAST YEAR AMORTIZATION - CURRENT PRICES														
				2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
	Aquisition Cost	Useful Life	Dep. Tax	0	1	2	3	4	5	6	7	8	9	10	11
Accumulated Inflation Factor				1,000	1,016	1,036	1,057	1,078	1,100	1,122	1,144	1,167	1,190	1,214	1,238
FIXED TANGIBLE ASSETS															
Transportation Equipments															
Vehicle 1	25 000,00 €	4	25%	25 000,00 €	- €	- €	- €	26 954,68 €	- €	- €	- €	29 176,62 €	- €	- €	- €
Vehicle 2	25 000,00 €	4	25%		25 400,00 €	- €	- €	- €	27 493,78 €	- €	- €	- €	29 760,15 €	- €	- €
Vehicle 3	25 000,00 €	4	25%							28 043,65 €	- €	- €	- €	30 355,35 €	- €
Vehicle 4	25 000,00 €	4	25%								28 604,53 €	- €	- €	- €	30 962,46 €
Sub-total	**100 000,00 €**			**25 000,00 €**	**25 400,00 €**	**- €**	**- €**	**26 954,68 €**	**27 493,78 €**	**28 043,65 €**	**28 604,53 €**	**29 176,62 €**	**29 760,15 €**	**30 355,35 €**	**30 962,46 €**
Lab Equipmens															
Flow Cytometer	45 000,00 €	7	14%	45 000,00 €	- €	- €	- €	- €	- €	- €	51 488,15 €	- €	- €	- €	- €
Incubator	13 000,00 €	7	14%	13 000,00 €	- €	- €	- €	- €	- €	- €	14 874,35 €	- €	- €	- €	- €
Fridge	2 091,00 €	7	14%	2 091,00 €	- €	- €	- €	- €	- €	- €	2 392,48 €	- €	- €	- €	- €
Pipettes	5 000,00 €	7	14%	5 000,00 €	- €	- €	- €	- €	- €	- €	5 720,91 €	- €	- €	- €	- €
Freezer	2 460,00 €	7	14%	2 460,00 €	- €	- €	- €	- €	- €	- €	2 814,69 €	- €	- €	- €	- €
Sub-total	**67 551,00 €**			**67 551,00 €**	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**	**77 290,57 €**	**- €**	**- €**	**- €**	**- €**
Administrative Equipment															
Printing Machine	529,00 €	5	20%	529,00 €	- €	- €	- €	- €	581,77 €	- €	- €	- €	629,72 €	- €	- €
Mobile Phone 1 (CEO)	146,26 €	5	20%	146,26 €	- €	- €	- €	- €	160,85 €	- €	- €	- €	174,11 €	- €	- €
Mobile Phone 2 (Clinical Trials Specialist)	146,26 €	5	20%		148,60 €	- €	- €	- €	- €	164,07 €	- €	- €	- €	177,59 €	- €
Mobile Phone 3 (QCM)	146,26 €	5	20%			151,57 €	- €	- €	- €	- €	167,35 €	- €	- €	- €	181,14 €
Mobile Phone 4 (Mkt Manager)	146,26 €	5	20%							164,07 €	- €	- €	- €	- €	181,14 €
Mobile Phone 5 (Sales Manager)	146,26 €	5	20%								167,35 €	- €	- €	- €	- €
Mobile Phone 6 (Sales Rep 1)	146,26 €	5	20%								167,35 €	- €	- €	- €	- €
Mobile Phone 7 (Sales Rep 2)	146,26 €	5	20%								167,35 €	- €	- €	- €	- €
Mobile Phone 8 (Sales Rep 3)	146,26 €	5	20%								167,35 €	- €	- €	- €	- €
Mobile Phone 9 (Sales Rep 4)	146,26 €	5	20%									170,69 €	- €	- €	- €
Mobile Phone 10 (sales Rep 5)	146,26 €	5	20%									170,69 €	- €	- €	- €
Mobile Phone 11 (Sales Rep 6)	146,26 €	5	20%										174,11 €	- €	- €
Phone 1	23,97 €	5	20%	23,97 €	- €	- €	- €	- €	26,36 €	- €	- €	- €	28,53 €	- €	- €
Phone 2	23,97 €	5	20%		24,35 €	- €	- €	- €	- €	26,89 €	- €	- €	- €	29,10 €	- €
Furniture	123,00 €	8	13%	123,00 €	- €	- €	- €	- €	- €	- €	- €	143,55 €	- €	- €	- €
Sub-total	**2 308,80 €**			**822,23 €**	**172,95 €**	**151,57 €**	**- €**	**- €**	**768,98 €**	**355,02 €**	**836,74 €**	**484,94 €**	**1 006,48 €**	**206,70 €**	**362,29 €**
FIXED TANGIBLE ASSETS	**169 859,80 €**			**93 373,23 €**	**25 572,95 €**	**151,57 €**	**- €**	**26 954,68 €**	**28 262,76 €**	**28 398,67 €**	**106 731,84 €**	**29 661,55 €**	**30 766,62 €**	**30 562,05 €**	**31 324,74 €**
INTAGIBLE ASSETS															
R&D Expenses															
Clinical Trials Phase IIB/III	8 000 000,00 €	20	5%					8 625 498,62 €	- €	- €	- €	- €	- €	- €	- €
Sub-total	**8 000 000,00 €**			**- €**	**- €**	**- €**	**- €**	**8 625 498,62 €**	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**
Industrial Property															
Patent	6 000 000,00 €	20	5%			6 217 920,00 €	- €	- €	- €	- €	- €	- €	- €	- €	- €
Sub-total	**6 000 000,00 €**			**- €**	**- €**	**6 217 920,00 €**	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**
INTANGIBLE ASSETS	**14 000 000,00 €**			**- €**	**- €**	**6 217 920,00 €**	**- €**	**8 625 498,62 €**	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**	**- €**
TOTAL ASSETS	**14 169 859,80 €**			**93 373,23 €**	**25 572,95 €**	**6 218 071,57 €**	**- €**	**8 652 453,31 €**	**28 262,76 €**	**28 398,67 €**	**106 731,84 €**	**29 661,55 €**	**30 766,62 €**	**30 562,05 €**	**31 324,74 €**

Source: Author

Table 43 - Depreciations of fixed assets, Commercialization

AMORTIZATIONS AND DEPRECIATIONS OF FIXED CAPITAL - REINVESTMENTS MADE AFTER THE LAST YEAR AMORTIZATION - CURRENT PRICES														
				2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
	Aquisition Cost	Useful Life	Dep. Tax	0	1	2	3	4	5	6	7	8	9	10	11
FIXED TANGIBLE ASSETS															
Transportation Equipments															
Vehicle 1	25 000,00 €	4	25%	6 250,00 €	6 250,00 €	6 250,00 €	6 250,00 €	6 738,67 €	6 738,67 €	6 738,67 €	6 738,67 €	7 294,15 €	7 294,15 €	7 294,15 €	7 294,15 €
Vehicle 2	25 000,00 €	4	25%		6 350,00 €	6 350,00 €	6 350,00 €	6 350,00 €	6 873,44 €	6 873,44 €	6 873,44 €	6 873,44 €	7 440,04 €	7 440,04 €	7 440,04 €
Vehicle 3	25 000,00 €	4	25%							7 010,91 €	7 010,91 €	7 010,91 €	7 010,91 €	7 588,84 €	7 588,84 €
Vehicle 4	25 000,00 €	4	25%								7 151,13 €	7 151,13 €	7 151,13 €	7 151,13 €	7 740,61 €
Sub-total	**100 000,00 €**			**6 250,00 €**	**12 600,00 €**	**12 600,00 €**	**12 600,00 €**	**13 088,67 €**	**13 612,12 €**	**20 623,03 €**	**27 774,16 €**	**28 329,64 €**	**28 896,24 €**	**29 474,16 €**	**30 063,64 €**
Lab Equipmens															
Flow Cytometer	45 000,00 €	7	14,29%	6 426,00 €	6 426,00 €	6 426,00 €	6 426,00 €	6 426,00 €	6 426,00 €	6 426,00 €	7 352,51 €	7 352,51 €	7 352,51 €	7 352,51 €	7 352,51 €
Incubator	13 000,00 €	7	14,29%	1 856,40 €	1 856,40 €	1 856,40 €	1 856,40 €	1 856,40 €	1 856,40 €	1 856,40 €	2 124,06 €	2 124,06 €	2 124,06 €	2 124,06 €	2 124,06 €
Fridge	2 091,00 €	7	14,29%	298,59 €	298,59 €	298,59 €	298,59 €	298,59 €	298,59 €	298,59 €	341,65 €	341,65 €	341,65 €	341,65 €	341,65 €
Pipettes	5 000,00 €	7	14,29%	714,00 €	714,00 €	714,00 €	714,00 €	714,00 €	714,00 €	714,00 €	816,95 €	816,95 €	816,95 €	816,95 €	816,95 €
Freezer	2 460,00 €	7	14,29%	351,29 €	351,29 €	351,29 €	351,29 €	351,29 €	351,29 €	351,29 €	401,94 €	401,94 €	401,94 €	401,94 €	401,94 €
Sub-total	**67 551,00 €**			**9 646,28 €**	**9 646,28 €**	**9 646,28 €**	**9 646,28 €**	**9 646,28 €**	**9 646,28 €**	**9 646,28 €**	**11 037,09 €**	**11 037,09 €**	**11 037,09 €**	**11 037,09 €**	**11 037,09 €**
Administrative Equipment															
Printing Machine	529,00 €	5	20%	105,80 €	105,80 €	105,80 €	105,80 €	105,80 €	116,35 €	116,35 €	116,35 €	116,35 €	125,94 €	125,94 €	125,94 €
Mobile Phone 1 (CEO)	146,26 €	5	20%	29,25 €	29,25 €	29,25 €	29,25 €	29,25 €	32,17 €	32,17 €	32,17 €	32,17 €	34,82 €	34,82 €	34,82 €
Mobile Phone 2 (Clinical Trials Specialist)	146,26 €	5	20%		29,72 €	29,72 €	29,72 €	29,72 €	29,72 €	32,81 €	32,81 €	32,81 €	32,81 €	35,52 €	35,52 €
Mobile Phone 3 (QCM)	146,26 €	5	20%			30,31 €	33,47 €	33,47 €	33,47 €	33,47 €	33,47 €	36,23 €	36,23 €	36,23 €	36,23 €
Mobile Phone 4 (Mkt Manager)	146,26 €	5	20%							32,81 €	32,81 €	32,81 €	32,81 €	32,81 €	36,23 €
Mobile Phone 5 (Sales Manager)	146,26 €	5	20%								33,47 €	33,47 €	33,47 €	33,47 €	33,47 €
Mobile Phone 6 (Sales Rep 1)	146,26 €	5	20%								33,47 €	33,47 €	33,47 €	33,47 €	33,47 €
Mobile Phone 7 (Sales Rep 2)	146,26 €	5	20%								33,47 €	33,47 €	33,47 €	33,47 €	33,47 €
Mobile Phone 8 (Sales Rep 3)	146,26 €	5	20%								33,47 €	33,47 €	33,47 €	33,47 €	33,47 €
Mobile Phone 9 (Sales Rep 4)	146,26 €	5	20%									34,14 €	34,14 €	34,14 €	34,14 €
Mobile Phone 10 (Sales Rep 5)	146,26 €	5	20%									34,14 €	34,14 €	34,14 €	34,14 €
Mobile Phone 11 (Sales Rep 6)	146,26 €	5	20%										34,82 €	34,82 €	34,82 €
Phone 1	23,97 €	5	20%	4,79 €	4,79 €	4,79 €	4,79 €	4,79 €	5,27 €	5,27 €	5,27 €	5,27 €	5,71 €	5,71 €	5,71 €
Phone 2	23,97 €	5	20%		4,87 €	4,87 €	4,87 €	4,87 €	4,87 €	5,38 €	5,38 €	5,38 €	5,38 €	5,82 €	5,82 €
Furniture	123,00 €	8	13%	15,38 €	15,38 €	15,38 €	15,38 €	15,38 €	15,38 €	15,38 €	15,38 €	17,94 €	17,94 €	17,94 €	17,94 €
Sub-total	**2 308,80 €**			**155,22 €**	**189,81 €**	**220,13 €**	**223,28 €**	**223,28 €**	**237,23 €**	**273,64 €**	**407,52 €**	**481,13 €**	**528,63 €**	**531,78 €**	**535,19 €**
TOTAL DEP. FIXED TANGIBLE ASSETS	**169 859,80 €**			**16 051,50 €**	**22 436,09 €**	**22 466,41 €**	**22 469,56 €**	**22 958,23 €**	**23 495,63 €**	**30 542,96 €**	**39 218,78 €**	**39 847,86 €**	**40 461,96 €**	**41 043,03 €**	**41 635,93 €**
INTAGIBLE ASSETS															
R&D Expenses															
Clinical Trials Phase IIB/III	8 000 000,00 €	20	5%					431 274,93 €	431 274,93 €	431 274,93 €	431 274,93 €	431 274,93 €	431 274,93 €	431 274,93 €	431 274,93 €
Sub-total	**8 000 000,00 €**			**- €**	**- €**	**- €**	**- €**	**431 274,93 €**	**431 274,93 €**	**431 274,93 €**	**431 274,93 €**	**431 274,93 €**	**431 274,93 €**	**431 274,93 €**	**431 274,93 €**
Industrial Property															
Patent Acquisition	4 000 000,00 €	20	5%			310 896,00 €	310 896,00 €	310 896,00 €	310 896,00 €	310 896,00 €	310 896,00 €	310 896,00 €	310 896,00 €	310 896,00 €	310 896,00 €
Sub-total	**4 000 000,00 €**			**- €**	**- €**	**310 896,00 €**	**310 896,00 €**	**310 896,00 €**	**310 896,00 €**	**310 896,00 €**	**310 896,00 €**	**310 896,00 €**	**310 896,00 €**	**310 896,00 €**	**310 896,00 €**
TOTAL DEP. INTANGIBLE ASSETS	**12 000 000,00 €**			**- €**	**- €**	**310 896,00 €**	**310 896,00 €**	**742 170,93 €**	**742 170,93 €**	**742 170,93 €**	**742 170,93 €**	**742 170,93 €**	**742 170,93 €**	**742 170,93 €**	**742 170,93 €**
TOTAL DEP. ASSETS	**12 169 859,80 €**			**16 051,50 €**	**22 436,09 €**	**333 362,41 €**	**333 365,56 €**	**765 129,17 €**	**765 666,56 €**	**772 713,89 €**	**781 389,71 €**	**782 018,80 €**	**782 632,89 €**	**783 213,96 €**	**783 806,86 €**

Source: Author