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Business plan of Nanotarg: a technological platform aiming to treat pancreatic cancer

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Abstract

Pharmaceutical industry is one of the most relevant activities and plays a major role in economics and the provision of global health. It is known that the processes of developing new compounds and its entry to the market are very complex and require specific guidelines that can only be provided by business and regulatory analytics. Although the key players in such industry are big companies, drug development is becoming a cooperative effort encouraging technology transfer since many compounds have their discovery origins in academia and small innovative companies, such as spin-offs.

In this thesis, a business plan of the nanotechnological platform Nanotarg is presented. This technology, whose origin arises from academic research in Universitat Pompeu Fabra, enables specific targeting to tumoral tissue in the pancreas and can potentially release the therapeutic gold standard to increase the survival rate of pancreatic cancer patients.

The goal of this project is to provide clear strategy lines for those researchers aiming to start the path of entrepreneurship. These business strategies derive from the exhaustive analysis of different features that affect pharmaceutical business development, among others, opportunity and market analysis are performed, as well as the SWOT and PESTEL analysis and financial projections to ensure profits and revenues.

Keywords

Keywords: entrepreneurship, spin-off, nanotechnological platform, specific targeting, pancreatic cancer

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1. EXECUTIVE SUMMARY

Nanotarg will increase the survival rate of pancreatic cancer patients by a site-specific release of the therapeutic gold standard, Abraxane. Pancreatic cancer has currently no solution and up to 91% of the patients die within 5 years. By 2025 is estimated to be the 3rd cancer-related death cause and worth $4,728.19 million by 2026.

2. OPPORTUNITY ANALYSIS

2.1. Clinical need

Pancreatic cancer is caused by the abnormal and uncontrolled growth of malignant cells in the pancreas [1]. This disease is mainly divided in two types: pancreatic ductal adenocarcinoma (PDAC), approximately 80% of all pancreatic tumours and occurring in the exocrine glands of the pancreas, and pancreatic neuroendocrine tumour found in the endocrine tissue of the pancreas [2].

Concretely, there is a huge problematic associated to PDAC since the approaches to detect, diagnose and treat the disease are not efficient enough and hence, the mortality associated to this disease is significantly high, almost equalling the incidence [2].

The fatal nature of the disease caused 432,242 deaths in 2018 worldwide, while a total amount of 458,918 new cases were reported that year around the world, considering both sexes and all ages [3]. This made pancreatic cancer the 7^{th} cause of world cancer-related deaths in 2018 [4] and it is believed to be the 2^{nd} and 4^{th} deadliest cancer in North America and Europe, respectively [5] [6]. Additionally, an upward trend in the mortality and incidence of the disease is revealed and the 5-years survival rate for PDAC is only around 9%, which creates an urgent need to approach the pathology [7] [4].

With regards to the diagnosis, there are no specific standard tools able to detect reliably the early-stage disease. Symptoms appear upon the progression of the pathology and consequently, PDAC is usually diagnosed at a late stage. Furthermore, the non-specific nature of the symptoms makes the differential diagnosis of PDAC even more complicated [8].

Treatment for PDAC depends on the type, the stage and the location of the tumour and it is typically complicated and inefficient due to late diagnosis. The main treatments are surgery, chemotherapy and radiotherapy and can be used alone or in combination [9]. However, immunotherapy and targeted therapy are also possible strategies. The current gold standard treatments are the chemotherapy regimens outlined in *Figure 1* [9]. Further information can be found in Appendix 14.1.

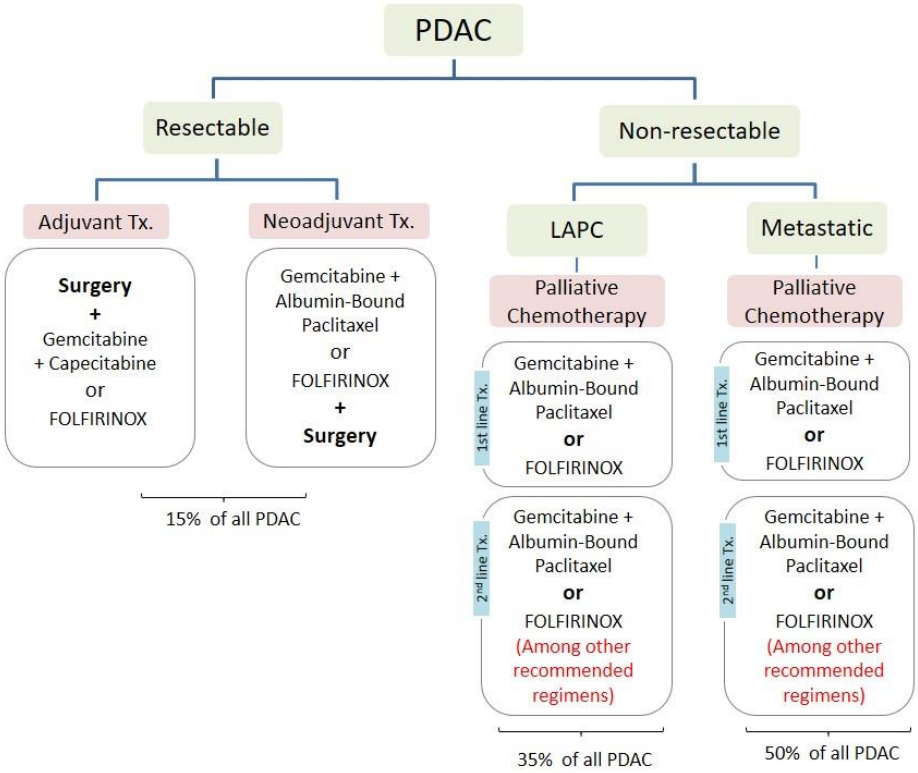


Figure 1: Gold Standard chemotherapy regimens for PDAC [10]. Tx: treatment. LAPC: Locally advanced pancreatic cancer.

To sum up, high aggressiveness, poor diagnosis, ineffective treatment and an upward trend of the global pancreatic cancer market size manifest strongly the urgent need to develop effective approaches to manage this pathology. All these factors related to PDAC leads to the conclusion that a multifunctional platform such as Nanotarg is potentially suitable.

2.2. Value proposition

The proposed solution is a nanotechnological platform that allows specific targeting to the pancreas via molecular recognition of an oncotarget exclusively expressed in the tumour and the apical site of the intestine (*Figure 2)*. Owing to this, the technology is

considered a specific targeted therapy. At a basic level, the technology consists in a capsule of a size < 400 nm that allows passive targeting, enhanced distribution and enhanced drug delivery efficiency (*Figure 3).* This capsule will specifically release the therapeutic gold standard Albumin-Bound Paclitaxel (nab-paclitaxel, brand name Abraxane), used in most of PDAC cases, >85%, according to *Figure 1*.

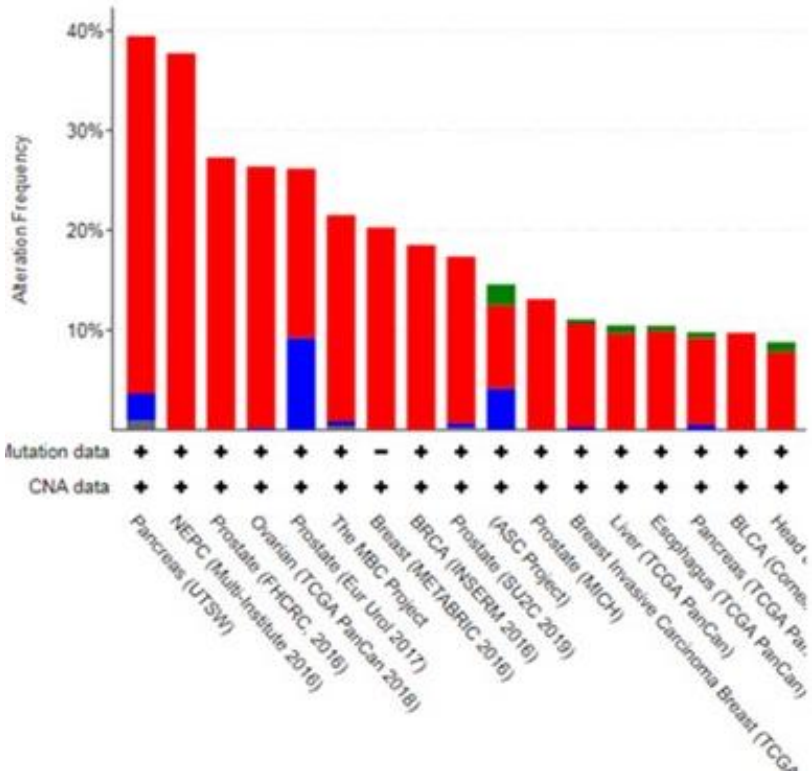


Figure 2: Biomarker

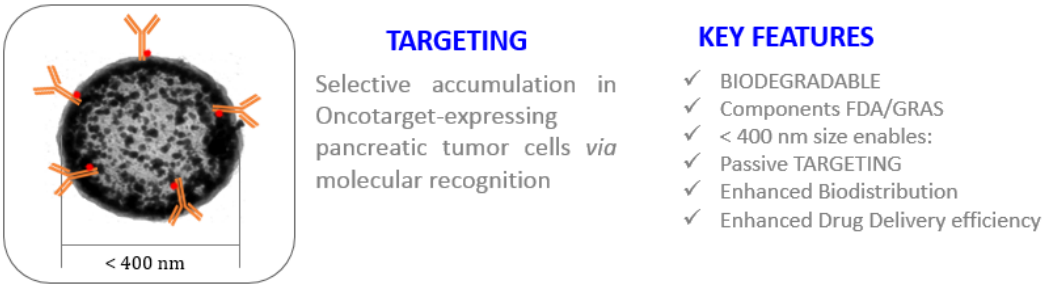


Figure 3: Schematization of the platform

2.3. Customer profile

Final users of Nanotarg are health care systems and the beneficiaries are patients. Therefore, the customer is a pharmaceutical company with whom a licensing agreement

of the Intellectual Property (IP) of the platform is appropriate. The therapeutic gold standard nab-paclitaxel, a nanomedicine, is manufactured and commercialized with the brand name Abraxane by the company Celgene and there is a soon patent expiration of such compound [11]. For this reason, a license agreement with Celgene seems convenient. However, in case that Celgene was not interested, Nanotarg could encapsulate the generic form of nab-paclitaxel or even a different chemotherapeutic agent and hence, it does not specifically rely on Celgene.

2.4. Competitive advantage

The targeting is the most valuable feature of the technology, concretely, the specific recognition by the platform of the oncotarget on the tumour and apical site of the intestine. In other words, this advantage is based on a combination of the oncotarget that is only expressed in the tumour and of the nanotechnological platform that recognizes the oncotarget and accumulates in the tumour. Direct competitors developing targeted therapy for PDAC are using indirect targeting approaches (See Section 4.2.2 Direct Competitors). Hence, Nanotarg is specific and more efficient.

3. PESTEL ANALYSIS

A PESTEL analysis is a widely known framework that enables to monitor and analyse macro-environmental (political, economic, social, technological, environmental and legal) factors that may have an impact on Nanotarg platform [12]. Different strategic conclusions arise from such analysis.

3.1. Factors

A brief summary of the macro-environmental factors is appreciable in *Table 1* and an exhaustive explanation is available in Appendix 14.2.

Table 1: Macro-environmental factors affecting Nanotarg platform

POLITICAL	ECONOMIC
• Type of health care system: public or private coverage. • Some drugs could not be included in health care systems of certain countries due to political decisions. • Poor investment in orphan diseases.	• Pancreatic cancer industry is estimated to grow. • Key players in pancreatic cancer industry are powerful pharmaceutical companies like Eli Lilly, Merck & Co., Roche, BMS, Celgene... • COVID-19 situation: Economical recession and higher investment in science and innovation
SOCIAL	**TECHNOLOGICAL**
• A shift in the disease pattern is occurring in emerging regions. • Average life span is increasing. • Human population growth. • Obesity rates increasing rapidly. • Tobacco use remains high. • Highest incidence in Europe and North America.	• Other treatment approaches (immunotherapy, targeted therapy, chemotherapy...). • Nanotarg is a multifunctional platform. development stages. • Nab-paclitaxel has limited efficacy.
ENVIRONMENTAL	**LEGAL**
• The platform is biodegradable. • All the platform components recognized as GRASE by the FDA/EMA. • Nab-paclitaxel environmental features are not fully investigated.	• FDA has not established standards for nanotechnology. • FDA is working on a regulatory program. • Orphan drug classification.

3.2. Strategic conclusions

It is known that the management of health depends on a country's political decisions and thus, there are different health care systems in the world [13]. This undoubtedly has an impact on the delivery of health that it is shaped by political decisions. It becomes especially controversial when related to the delivery of treatments for orphan diseases, such as pancreatic cancer [14]. As an example, the case of Onivyde, an effective treatment for PDAC that is not used within the Spanish health system due to decisions taken by the Ministry of Health [15]. For this reason, it is reasonable to think that political

factors could play an important role on the implementation of any potential new treatment for PDAC, such as Nanotarg.

With regards to economic factors, the pharmaceutical industry is a top performing sector and oncology is the largest proportion of pharmaceutical development [16]. Those companies who successfully approach PDAC, for instance Celgene, are top companies in such industry [17]. However, the world economy is now on recession due to the COVID-19 crisis. Still, the nature of this emergency could lead to higher investments on science an innovation having a positive impact on companies such as Nanotarg.

Socially, in emerging regions the disease pattern will suffer a shift and pathologies like cancer will rise [18]. Oncology is one of the most important sectors and the market of drugs addressing cancer will certainly increase. In addition, an increasing life span of population will undoubtedly have an impact since it is known that the risk of developing the disease increases with age [4] [19]. Other risk factors like tobacco use, still high in many countries, and obesity, growing globally, support the idea that pancreatic cancer market is estimated to grow in the next years [20][21] [22].

The three main treatment lines approaching pancreatic cancer are immunotherapy, chemotherapy and targeted therapy. However, most of the marketed drugs addressing PDAC are chemotherapy agents such as nab-paclitaxel [9] [11], the gold standard therapy that Nanotarg aims to deliver. Still, a variety of drugs are now on clinical trials and technology surveillance should become a key activity.

However, the efficacy of the compound nab-paclitaxel is limited and not fully understood [23]. Due to this, it must be considered that further research in this compound may have an impact on Nanotarg technology.

Focusing on Nanotarg's functionality, it is obvious that such platform could develop other potential activities if further studied. It is a multifunctional platform and it is crucial to consider that the specific targeting could be used with different purposes. For this reason, IP needs to be protected and patented before any licensing agreement with Celgene.

Environmentally, the impact of the platform must be exhaustively addressed in further stages since agencies like FDA require Environmental Assessments as part of any drug application [24]. However, Nanotarg is a biodegradable platform and all the components are recognized as GRASE (Generally Recognized As Safe and Effective) by the FDA.

With regards to legal factors, there are no established standards for the regulatory of nanotechnologies [25]. Most of the drugs addressing PDAC are designated as orphan drugs, owing to the rarity of the disease [26]. Furthermore, this designation allows manufacturers to qualify for various incentives, including tax credits for qualified clinical trials and 7 years of market exclusivity [27]. For this reason, the orphan drug designation is a suitable regulatory option for Nanotarg. However, as Nanotarg is a platform, other regulatory options have to be considered.

4. MARKET ANALYSIS

4.1. Niche market

As previously mentioned, the gold standard treatment regime for PDAC is chemotherapy. Concretely, the compound nab-paclitaxel, commercialized by Celgene with the name of Abraxane, is standardly used in combination with gemcitabine in approximately >85% of the PDAC cases, as appreciable in *Figure 1*. Therefore, the market for Nanotarg is a targetable portion of PDAC broader market, as presented in *Figure 4*, and can potentially account for more than 85% of PDAC cases.

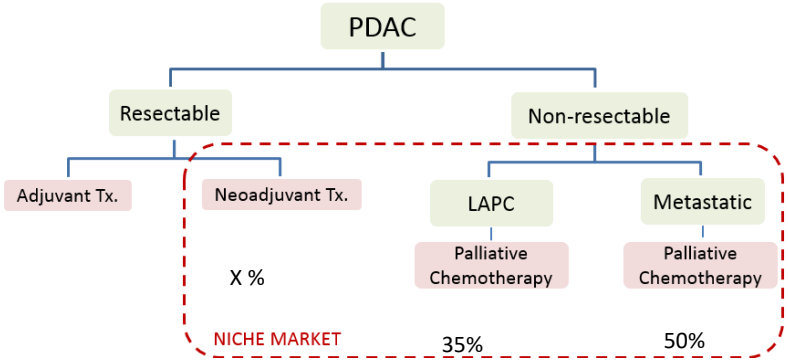


Figure 4: Niche market for Nanotarg

4.2. Competitor analysis

It is crucial in business strategy to determine the strengths and weaknesses of the competitors within a certain market, to understand the distinct advantage of a technology, in this case, Nanotarg. A first step in this section is to identify direct and indirect competitors. An exhaustive screening of marketed and potential new compounds for the treatment of PDAC is available in Appendix 14.3. However, *Figure 5* provides a brief summary of the different compounds and therapy agents addressing the pathology.

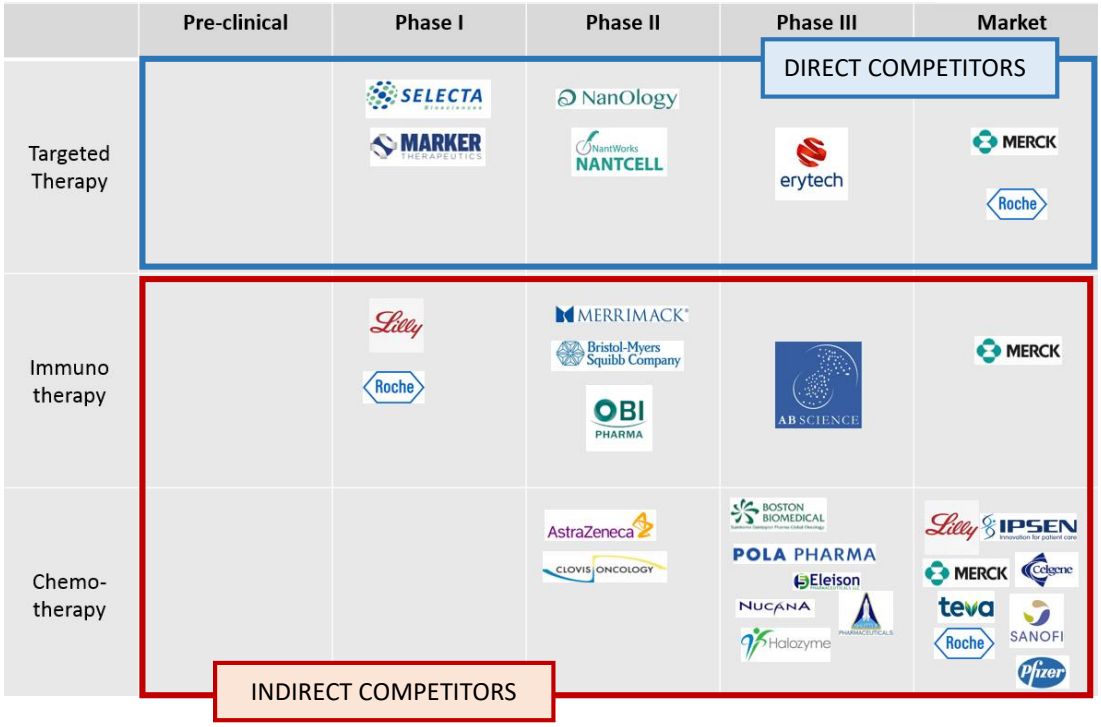


Figure 5: Direct and Indirect competitors of Nanotarg by type and clinical phase

4.2.1. Direct competitors' grid

A competitors' grid (*Table 2)* reveals the distinct advantages of the technology compared to direct competitors. Moreover a positioning map (*Figure 6)* shows graphically the information collected in *Table 2*.

Table 2: Competitors' grid

	DIRECT COMPETITORS				
FEATURES	**Nanopac**	**NANT Vaccine**	**Lynparza**	**Tarcevas**	**Eryaspase**
Targeting	Non-specific	Non-specific	Non-specific	Non-specific	Non-specific
Range of application	35% of PDAC	50% of PDAC	4-8% of PDAC	<85% of PDAC	50% of PDAC

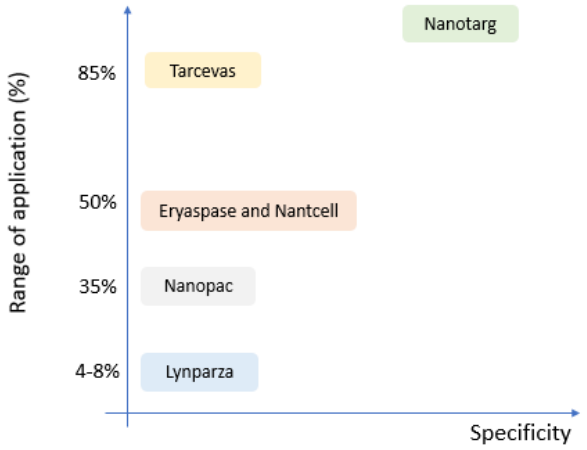


Figure 6: Positioning Map of Nanotarg and its direct competitors

As appreciable, one of the distinct attributes of Nanotarg is the specific targeting, the specific recognition of the oncotarget on the tumour by the platform. Nanotarg solution is based on a combination of the oncotarget that is only expressed in the tumour and of the nanotechnological platform which recognizes the oncotarget and accumulates in the tumour. Other direct competitors developing targeted solutions use indirect mechanisms for targeting. Nanotarg solution is through molecular recognition thus being more specific and more efficient. Besides, through the nano-state, there is also a passive targeting effect associated.

On the other hand, another key feature of Nanotarg is the range of application, which is higher than those of the direct competitors. While Nanotarg would be applicable to approximately 85% of all PDAC patients, other strategies target a smaller portion of cases, as appreciable in *Table 2.*

4.2.2. Direct competitors

Direct competitors are those businesses competing for the same potential market (or a part of it) and offering similar solutions, in other words, other targeting agents that aim to treat PDAC [28]. Nowadays, there are two targeting compounds in the market, Lynparza and Tarcevas, manufactured by Merck and Co. and Roche Holding AG respectively. However, other direct competitors still on clinical trials also need to be considered to determine the distinct attributes that allow Nanotarg to outperform its direct competitors. For this reason, direct competitors appear in *Table 3* and are analysed in further sections. Detailed information is available in Appendix 14.3.

Table 3: Direct competitors. [29][30][31][32][33][34]

Marketed targeting agents for PDAC	Company	Total Revenue (million USD)
Lynparza	Merck and Co.	$42, 294 million
Tarcevas	Roche Holding AG	$57,000 million
Targeting agents in clinical trials for PDAC	**Company**	**Total Revenue (million USD)**
Nanopac	NanOlogy	<$1 million
NANT Cancer Vaccine	NantCell	$3 million
Eryaspase	Erytech Pharma	$11 million

4.2.2.1. Lynparza

Lynparza is a Merck and Co. treatment based in the molecule olaparib. It is currently used to treat metastatic pancreatic cancer with a certain type of abnormal inherited BRCA gene, which represents about 4% to 8% of the cases of PDAC. With regards to the targeting, it targets the inhibition of the poly ADP ribose polymerase (PARP) in cancer cells. This is a non-specific targeting mechanism [29].

4.2.2.2. Tarcevas

Tarcevas is a Roche Holding AG therapy which is typically administered with gemcitabine for patient whose PDAC cannot be surgically removed and who have not received previous chemotherapy [30]. It is only used for non-resectable PDAC with no previous dose of chemotherapy, which is undoubtedly under 85% of the PDAC cases. Moreover, the targeting is non-specific for pancreatic cancer since it only targets a protein on general cancer cells, the Epidermal Growth Factor Receptor (EGFR).

4.2.2.3. Nanopac

The targeted therapy from NanOlogy named Nanopac, which now has finished clinical trial phase II, aims to be injected using endoscopic ultrasounds guides and deliver intratumorally the treatment (Sterile Nanoparticulate Paclitaxel) for locally advanced pancreatic cancer (LAPC). According to *Figure 1*, it could potentially be used in

approximately 35% of the cases. Furthermore, the targeting is done by injecting which is a non-specific mechanism [31].

4.2.2.4. Nantcell

The therapy NANT Cancer Vaccine, from Nantcell Company, is a combination of immunotherapy and the delivery of a low-dose radiation and chemotherapy with tumour associated antigen vaccines and natural killer cells, to induce immunogenic cell death [32]. For the moment, it is unknown the scope of the application of such treatment, however, clinical trials have only considered metastatic pancreatic cancer [33], which is a 50% of the total amount of PDAC cases, according to *Figure 1*.

4.2.2.5. Eryaspase

From the company Erytech Pharma, Eryaspase is currently ongoing clinical trials. It consists of L-asparaginase encapsulated inside donor-derived red blood cells and targets the cancer cell's altered asparagine and glutamine metabolism, which makes targeting non-specific since these metabolisms also play roles on other cancer types and processes. The trial is focused only on patients with metastatic PDAC, a 50% of the total. However, it is a second line treatment, so it could potentially be administered after Nanotarg and therefore may not be a real competitor [34].

4.2.3. Indirect competitors

Indirect competitors are those companies competing for the same potential market (or a part of it) and offering different solutions [28]. Although Abraxane and Gemzar (brand name for gemcitabine) are the chemotherapy gold standard agents, there are many other companies addressing with chemotherapy the same niche market as Nanotarg.

However, it is fundamental to understand that chemotherapy agents can be seen as potential allies and not only competitors since any chemotherapy agent is a potential *cargo* for the platform.

On the other hand, immunotherapy is also a possible strategy to treat PDAC and although it is not considered a gold standard therapy right now, it could become more important in the future. By now, there is only one marketed immunotherapy drug addressing PDAC, named Keytruda and marketed by Merck and Co. [35]. This drug is now available for

unresectable PDAC related to certain genetic mutations and the percentage of users is very small [36].

In *Table 4* appear the indirect competitors (including Abraxane), those pharmaceutical companies aiming to treat PDAC using either chemotherapy or immunotherapy. It is easy to appreciate that these companies are all top pharmaceutical businesses with huge annual revenues.

Table 4: Indirect competitors. [37] [38] [39] [40] [41] [42]

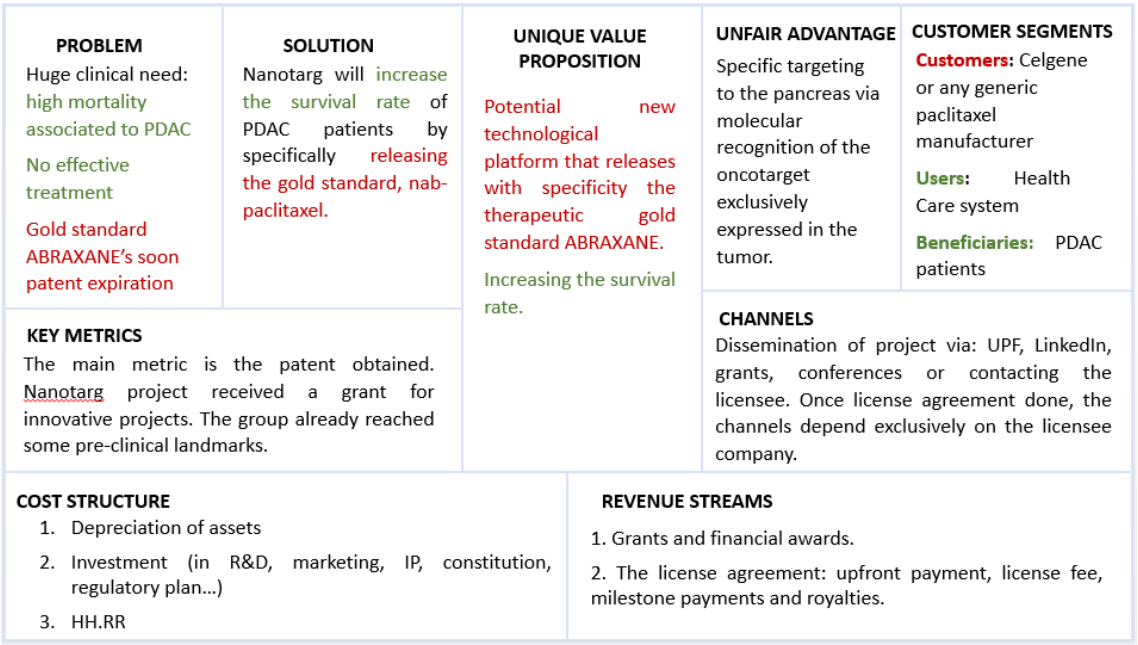
Marketed chemotherapy drugs for PDAC	Company	Active Ingredient	Total Revenue (million USD)
Gemzar	Elli Lilly and Company	gemcitabine	$24,555.7 million
Abraxane	Celgene Corporation	nab-paclitaxel	$15,281 million
Xeloda	Roche Holding AG	capecitabine	$57,000 million
Adrucil	Teva Pharmaceuticals	5-FU(fluorouracil)	$18,271 million
Camptosar	Pfizer Inc.	Irinotecan	$53,600 million
Marketed immunotherapy drugs for PDAC	**Company**	**Active Ingredient**	**Total Revenue (million USD)**
Keytruda	Merck and Co.	pembrolizumab	$42,294 million

5. BUSINESS MODEL

In this section a Business Model Canvas is used to describe, design and pivot the business model of Nanotarg. It is important to have in mind that the team that developed Nanotarg aims to set up a new spin-off company from the UPF and reach a license agreement with Celgene. A business model is appropriate to focus on the essential features of the business and clear irrelevant data [43]. It will provide a picture of the Nanotarg business idea and better understanding of weaknesses and strengths.

5.1. Lean Canvas

As Nanotarg project is still on its infancy it is more suitable to perform a Lean Canvas, an adaptation from Business Model Canvas by Ash Maurya focused on entrepreneurship and start-up business [43][44]. In *Figure 7* a schematized Lean Canvas is appreciable.



F*igure 7: Lean Canvas Business Model for Nanotarg*

5.1.1. Block I: Costumer Segments and Problem

A clear distinction between customers, users and beneficiaries needs to be clarified initially. Firstly, the customer is a pharmaceutical company aiming to reach a license agreement with Nanotarg. As mentioned, Celgene is a suitable company for such agreement. However, a customer could be any other company manufacturing paclitaxel. In other words, our Business Model involves Celgene but it does not rely uniquely on them. Secondly, those who will use Nanotarg platform are health care professionals, or in other words, health care systems. Finally, the recipients of the therapy are those who will experience the benefits, PDAC patients.

The problematic affecting users and beneficiaries is that there is no effective treatment for PDAC, and the mortality associated to this pathology is extremely high. With regards to the customers, the main problem is the soon patent expiration of the therapeutic gold standard Abraxane, one of the company's top compounds, and hence the loss of market exclusivity.

It is crucial to understand that this business model shows up that the problems of the customers and those of the users and beneficiaries may be different but have a common solution, Nanotarg.

5.1.2. Block II: Solution and Unique Value Proposition

The solution can be described as the way Nanotarg delivers value to customers, users and beneficiaries [45]. Nanotarg will increase the survival rate of PDAC patients, and thus, solve the problematic of high mortality. Secondly, it delivers value to customers by specifically releasing the cargo, manufactured by costumers (e.g nab-paclitaxel in the case of Celgene).

With regards to the Unique Value Proposition (UVP), it focuses on how Nanotarg solution gets the attention of customers, users and beneficiaries. It is easy to derive this UVP by figuring out the intersection between the problems and the solution, focusing not on the top features of the solution but on the finished story benefits that the costumers/users and beneficiaries derive from the solution [45].

With regards to customers, Nanotarg offers a new technological platform to release a certain compound (e. g nab-paclitaxel, contrast agent…), opening therefore the possibility of having exclusivity to a potential and more effective new treatment/diagnosis addressing PDAC. Furthermore, the nature of this platform is also part of the UVP since it involves specific targeting (i. e the combination of the biomarker and the nanocarrier) which leads to different solutions for treatment or diagnosis.

On the other hand, the value offered to users and beneficiaries is the increase of survival rate of PDAC patients.

5.1.3. Block III: Revenue Streams

This section refers to the source of revenues of the company [45]. As an emerging company, the initial income of Nanotarg consists on governmental grants or financial awards. An example of that could be the Knowledge and Industry Grant which has recently awarded Nanotarg. On the other hand, the income of Nanotarg also depends on the license agreement. Considering the nature of license agreements between pharmaceutical companies and research groups, according to Global Data Intelligence

Center, it is reasonable to think that such agreement would fulfil the following payments [46][47][48].

- Upfront payment: The customer pays for a part of the deal at the beginning of the agreement.
- License fee
- Milestones: Income only released if determined benchmarks are reached.
- Royalties: Percentage (normally up to 5%) of the net sales that the customer will obtain if a compound finally reaches the market.

5.1.4. Block IV: Channels

This section focuses on how Nanotarg builds a path to customers, in other words, the channels used to look for potential clients or key actors involved in revalorizing the technology. This can be accomplished by the dissemination of the project via the UPF, LinkedIn and participating to governmental grants, conferences, patient associations, entrepreneurship fairs... Once the license agreement is accomplished, the channels that aim to commercialize, disseminate and promote the technology to users and beneficiaries depends exclusively on Celgene. However, dissemination could still be an activity for the company.

5.1.5. Block V: Key Metrics

Success method of the product [45]. The key activity of the company is to reach a license agreement with Celgene. With no legal protection of the intellectual property of Nanotarg, there is no possible commercialization. Hence, the main metric is the patent of the technology.

Other secondary metrics are the fact that Celgene company already discovered Nanotarg and contacted and the obtainment of a 100.000 € Knowledge and Industry Grant [49], focused on innovative projects with potential for being incorporated into the production sector. On the other hand, the research group has already achieved some of the landmarks related to the preclinical development of Nanotarg.

5.1.6. Block VI: Cost Structure

Nanotarg as a UPF spin-off company will have to afford the cost of the value proposition [45]. Initially, the assets of the company would need to be depreciated. Secondly, investment will be fundamental to carry out R&D activities, a regulatory plan, marketing activities and IP, among others. Finally, costs will be associated to HR and utilities as well.

5.1.7. Block VII: Unfair advantage

The unfair advantage can also be understood as a competitive advantage, in other words, how a company accomplishes the value proposition and defends against competition [45]. In this case, the unfair advantage is the specific targeting to the pancreas via molecular recognition of the oncotarget exclusively expressed in the tumour and apical site of the intestine. In other words, the unfair advantage is combination between the biomarker and the nanocarrier. Also, an IP strategy of such feature is crucial to ensure that this feature cannot be copied, and it is valuable to the licensee.

6. STRATEGIC PLAN OF NANOTARG

Entrepreneurship and strategy may be understood by some as a dichotomy, however, entrepreneurship without strategy would undoubtedly lead to a very chaotic situation. A strategic plan is crucial to understand the direction of an organization, to set priorities and focus energy and resources towards common goals [50]. An effective strategic plan and its sections are available in this section [51].

6.1. Vision statement

Nanotarg will become a successful spin-off that enhances peoples' quality life transferring research outcomes to society. It will impact on the human wellbeing through excellence in science and generation of knowledge.

6.2. Mission statement

Nanotarg seeks to properly use scientific outcomes to deliver healthcare to society. It strives to commit to the improvement of quality life through the generation of innovative pharmaceutical products.

6.3. Core values

6.3.1. Technology transfer

There is huge accumulated knowledge in universities that if properly disseminated to society could bring unique value to people's life. It is part of our mission to properly transfer this knowledge into the marketplace since the only way to return investment from society into science is by generating solutions to their problems and transferring technologies and knowledge.

6.3.2. Innovation and experimentation

The company seeks for an innovative attitude present at different levels of the company. Furthermore, experimentation is fostered since it is the quickest technique to validate ideas or products.

6.3.3. Teamwork and autonomy

The idea of Nanotarg as a technological platform was born from the ideas of two separate research groups from UPF. Cooperation and teamwork are core features and multidisciplinary teams are desirable and the authority is decentralized.

6.3.4. Honesty and integrity

Ethical standards ensure that all the company's products and operations fulfil the requirements and procedures to produce quality drugs.

6.3.5. Respect for human life

The goal of the company is to provide healthcare and it is guided by the commitment to work for and improve human life.

6.3.6. Gender equality

It is a core value to extend gender equality throughout all the levels of the organization. Our company is extremely aware of the importance of developing safe spaces and gender/race/identity discrimination is unacceptable. This undoubtedly will improve the work environment. Woman leadership also plays an important role in the company since we are committed to enhance the role of woman in high-tech positions.

6.3.7. Responsible Research and Innovation (RRI)

Within the company's projects, the implications and social expectations are exhaustively considered in order to finally foster the design of inclusive and sustainable global innovation and research. Projects include the participation of multidisciplinary actors such as researchers, citizens, policy makers, business, etc. and considers effects and potential impacts on the environment and society [52].

6.3.8. Exponential organization

The company relies in new organizational techniques which allow a company to scale as quickly as tech does and causes a large impact compared to conventional companies [53]. Furthermore the company aims to cooperate with other emerging companies (start-ups) to obtain every expertise not belonging to Nanotarg.

6.4. SWOT analysis

It is a crucial activity within companies to perform a SWOT analysis. It is a very simple tool that will lead to a clear business strategy. Basically, it is a compilation of the strengths and weaknesses of a company (or emerging idea) and the opportunities and threads present in the external business environment. In *Table 5* a summarized SWOT analysis is appreciable.

Table 5: SWOT analysis of Nanotarg

STRENGTHS	WEAKNESSES
• Strong and unique value proposition different from other alternatives • Multifunctional technological platform	• Emerging company: lack of resources • Regulatoty pathway not yet identified
OPPORTUNITIES	**THREATS**
• Strong clinical and market need • Soon patent expiration of Abraxane. • Global PDAC industry expected to grow • PDAC is an orphan disease	• Uncertainty • COVID-19 crisis • Nab-paclitaxel mechanisms not fully understood • Stigma assoaciated to the nano state

6.4.1. Strengths

Nanotarg's value proposition is very strong and unique. The platform offers a specific mechanism of targeting and a high degree of application, since it is applicable to >85% of the PDAC cases approximately. Moreover, the platform is multifunctional and could potentially be used with other purposes (as a contrast, targeting other tumours, etc.) that need to be exhaustively studied.

6.4.2. Weaknesses

Nanotarg platform is an emerging entity from researchers at UPF, which means that economic resources are scarce. Furthermore, it is still on its infancy and extra efforts need to be done in order to acquire resources from grants.

On the other hand, regulatory issues are almost market barriers for innovative technologies, such as Nanotarg. Particularly, there is no clear regulatory strategy for this platform and it is vital to soon find the proper one.

6.4.3. Opportunities

The clinical need surrounding PDAC is strong. The existing treatments are clearly not effective and approximately <91% of patients die within 5 years [4]. Moreover, the soon expiration of the therapeutic gold standard Abraxane, manufactured by Celgene could trigger a license agreement.

On the other hand, the global pancreatic cancer industry, and oncology in general, is estimated to grow in the following years.

With reference to regulations, there is no specific standards for nanomedicine such as Nanotarg. As PDAC is considered an orphan disease, the orphan drugs designation is suitable and desirable, since it provides incentives, including tax credits for qualified clinical trials and 7 years of market exclusivity [27].

6.4.4. Threads

Uncertainty, at different levels, is the main thread that Nanotarg platform faces. Firstly, it is widely known that only 14% of drugs ongoing clinical trials end up with approval, this means that there is a huge degree of uncertainty [54].

In addition, nanomedicine tend to be stigmatized in some regions due to its novelty and potential. This is a thread for anyone trying to work with nanomedicine.

Furthermore, the COVID-19 crisis may have changed the interest of top pharmaceutical companies. Finally, Abraxane mechanisms are not fully understood at the moment. Any advance could lead to uncertain consequences.

6.5. Strategic approach of Nanotarg

Michael Porter described in 1985 in his book "Competitive Advantage: Creating and Sustaining Superior Performance" the four strategic approaches that can be pursued by organizations [55]. These are lower cost strategy, differentiation strategy and focused (or not) strategy. A lower cost strategy means that a company provides lower cost products than its competitors. On the other hand, a differentiation strategy is about differentiating the company itself owing to certain key features valued by the costumers that may (or not) command a higher price. With regards to focus, a company may approach a focused strategy, providing a product to only a certain section of market, or an industry-wide strategy, offering the product to many market sections. In *Figure 8* a schematic representation is available.

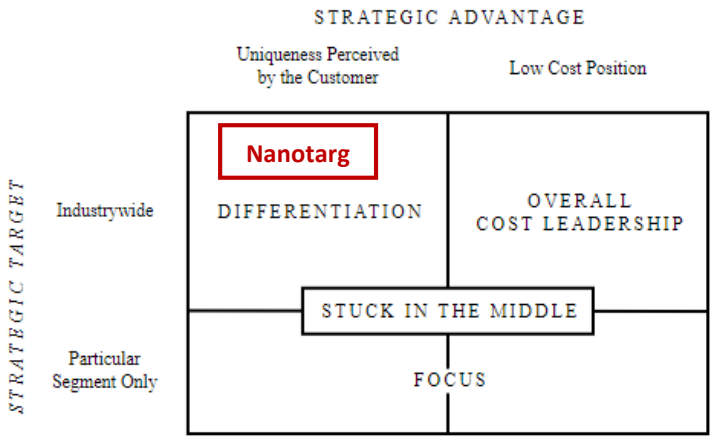


Figure 8: Porter's four strategic approaches [56]

In the case of Nanotarg, a differentiation strategy is more suitable. The unique quality of the offered product is the specific targeting of the tumour by the platform. This key feature is the unfair advantage of the product and differentiates the company form its competitors since none of them approach PDAC with specific targeting. Furthermore, as it is a multifunctional platform it could address many market niches, making it an industry wide

approach. In other words, as the platform could be used with different purposes (e.g diagnosis or treatment), the target is wide.

6.6. Action plans

Considering the SWOT analysis and the industry-wide differentiation approach of Nanotarg, in this following section the action plans that the company should most urgently address are stated.

6.6.1. IP protection plan

It is fundamental for organizations trying to approach the differentiation strategy to have a strong IP protection plan. Particularly, Nanotarg platform needs two different IP approaches due to the width of the solution. A first patent of the capsule itself has already been granted and is appropriate to protect the core features of the platform. Secondly, a second patent is suitable to trigger the license agreement with Celgene or any paclitaxel manufacturer. This second patent of the platform will use paclitaxel as *cargo*. It is appropriate to trigger the license agreement and it is the one that could potentially be licensed to Celgene, and hence, the company's product.

6.6.2. License agreement

It is fundamental to reach a license agreement. The most suitable company is Celgene, but could be another. By now, Nanotarg has already reached contact with this company. On the other hand, Nanotarg will not become a company until a costumer is found.

6.6.3. Preclinical phase

It is appropriate to start the preclinical phase as soon as possible to assess issues such as scalability, synthesis, regulatory, effectiveness, among others. The mentioned studies would be performed using the Nanotarg platform and nab-paclitaxel. Some of the cost associated to the company derive from these mentioned activities.

7. COMPANY DESCRIPTION

Nanotarg will become a spin-off company once a customer (the licensee) interested in the product (the 2nd patent) is found. If this is accomplished it will become a new company

and UPF will transfer the assets and the IP's to the company via the *contribution-in-kind* [57] strategy. Then, a license agreement will be reached.

8. FINANCIAL PLAN

Financial planning or forecasting is the most important activity in business planning and aims to reveal the picture of the finances of a company to assess its profitability and solvency [58]. It is crucial to understand that in this particular case, a financial plan can only be done by taking assumptions and premises, hence there is no Nanotarg company yet and therefore, no real data available. For this reason, the totality of the plan is an estimation based on premises which aim to be as accurate as possible.

It is important to consider that the structure of this section derives from the study of Pérez from Pérez Silvestre, V. (2013). "Plan financiero EOI". EOI Escuela de Negocios [59]. In order to obtain more detailed information of the Financial Plan, find Appendix 14.4.

8.1. Estimated development and general assumptions

It is known that the process of drug research and development may take at least 10 years [60]. Moreover, some studies point that oncology drug development could take up even to 13 years [61]. Nanotarg has already managed through the first 2-3 years of development and thus, it is assumed that the potential new treatment for PDAC could reach the marketplace at 2031.

As mentioned in previous sections, Nanotarg will only constitute as a spin-off company once a customer is found. Communication with Celgene is ongoing now and the 2nd IP process is progressing, therefore, it is reasonable to think that such agreement could take place in 2022. Just before that, Universitat Pompeu Fabra (UPF) would transfer the assets to the new-born company (including IP) via the *contribution in-kind* [57] strategy. Then, Nanotarg would become a company itself ready to reach a license agreement with Celgene (or another company). From that moment and on, Celgene would be responsible of the further development of the paclitaxel encapsulating platform. In *Figure 9*, the estimated timeline and development of the technology is appreciable.

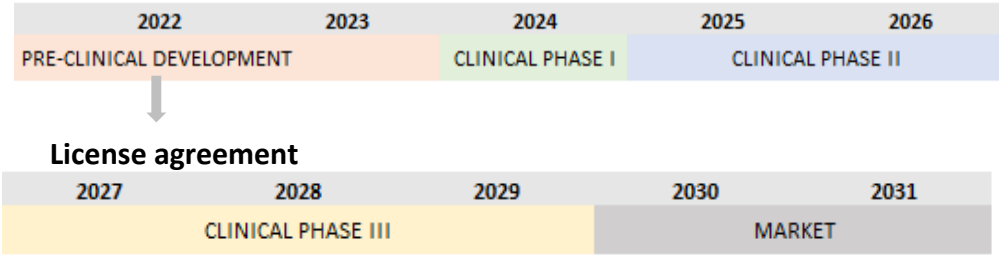


Figure 9: Estimated development of Nanotarg

8.2. Starting Balance Sheet

A Balance Sheet is the *kick-off* point in any Financial Plan and it aims to report the estimated assets and liabilities of the company/group to understand its financial position [62]. In *Table 6*, the estimated starting balance sheet is appreciable. Detailed information can be found in Appendix 14.4 (Section 15.4.1).

Table 6: Balance Sheet of Nanotarg after a license agreement is reached in 2022

			% VAT	VAT import
ASSETS	**Noncurrent assets**			
	Fixed assets			
	Equipment	1.500,00 €	21%	315,00 €
	Intangible assets			
	Web page	1.000,00 €	21%	210,00 €
	Intellectual Propery (1st Patent)	15.000,00 €	0%	- €
	Current assets			
	Liquid assets			
	Initial Treasury	3.000,00 €		
	VAT	525,00 €		
	TOTAL ASSETS:	**21.025,00 €**		
LIABILITIES	**Current liabilities:**			
	Equipment	1.500,00 €		
	Web page	1.000,00 €		
	VAT	525,00 €		
	Intellectual Propery (1st Patent)	15.000,00 €		
	TOTAL LIABILITIES:	18.025,00 €		

8.3. Investment and depreciation

It is obvious that to ensure the proper development of the Nanotarg entity, investment will need to be done to obtain profits in the future. The estimated investment plan is appreciable in *Table 7.*

As a technological company the investment is focused on R&D activities to perform the preclinical phase, to obtain the 2nd IP (using paclitaxel as cargo), to afford the constitution expenses and to perform dissemination and marketing. However, a depreciation process

would undoubtedly take place within the following years and therefore, depreciation costs should be taken into consideration in the Profit and Loss statement in section 9.6 in this document. Detailed information is available in Appendix 14.4 (Section 15.4.2 and 15.4.3).

Table 7: Investment Plan

Intangible assets	Year	Financial Value (€)
Intellecutal Property (2nd patent)	2022	15.000,00 €
R&D activities	2022-2025	200.000,00 €
Constitution expenses	2022	500,00 €
Marketing/Dissemination activities	2023-2027	10.000,00 €

8.4. Human Resources

As any other company, costs associated to salaries and employees have to be taken into consideration. Concretely, as it is an emerging company, it is assumed that only 3 people are involved, 2 partners and 1 employee. In *Table 8* and *Table 9* the total costs related to human resources (HR) in each year over the period 2022-2031 are available. Detailed information is available in Appendix 14.4 (Section 15.4.4).

Table 8: HR costs from 2022 to 2026

	2022	2023	2024	2025	2026
Partners					
Partner 1	3.000,00 €	3.090,00 €	3.182,70 €	3.278,18 €	3.376,53 €
Partner 2	3.000,00 €	3.090,00 €	3.182,70 €	3.278,18 €	3.376,53 €
Employees					
Postdoc	33.000,00 €	35.437,50 €	35.437,50 €	35.437,50 €	37.209,38 €
TOTAL	**39.000,00 €**	**41.617,50 €**	**41.802,90 €**	**41.993,86 €**	**43.962,43 €**

Table 9: HR costs from 2027 to 2031

	2027	2028	2029	2030	2031
Partners					
Partner 1	3.477,82 €	3.582,16 €	3.689,62 €	3.800,31 €	3.914,32 €
Partner 2	3.477,82 €	3.582,16 €	3.689,62 €	3.800,31 €	3.914,32 €
Employees					
Postdoc	37.209,38 €	41.023,34 €	41.023,34 €	41.023,34 €	43.074,50 €
TOTAL	**44.165,02 €**	**48.187,65 €**	**48.402,58 €**	**48.623,96 €**	**50.903,14 €**

8.5. Income

The primary source of income for Nanotarg derives from the license of the product, which is the 2nd IP. Considering data obtained in the Global Data Intelligence Center concerning the nature of two real license agreement between a pharma company and a research group [46] [47], an estimated license agreement for this particular case is appreciable in *Table 10.* Both the total deal of the agreement (3 USD million) and the monetary quantities each associated to a certain imbursement are estimated according to the mentioned license agreements and the proportions found there. Detailed information about it can be found in Appendix 14.4 (Section 15.4.5).

Secondly, some of the revenues are assumed to come from grants or financial rewards offered by governmental institutions. In this particular case, it is assumed that 150.000€ could be obtained by 2023. This amount of money is assumed to be used to perform the R&D activities mentioned in the Investment Plan (*Table 7).*

Table 10: Estimated license agreement with Celgene

License agreement	% of total deal	3.000.000,00 USD	Total in €	Year
1. Upfront payment	3,0%	90.000,00 USD	82.800,00 €	2022
2.License fee	2,0%	60.000,00 USD	55.200,00 €	2022
3. Milestones				
M1: Clinical Trial I	8%	240.000,00 USD	220.800,00 €	2024
M2: Clinical Trial II	15%	450.000,00 USD	414.000,00 €	2025
M3: Clinical Trial III	27%	810.000,00 USD	745.200,00 €	2027
M4: Market	45%	1.350.000,00 USD	1.242.000,00 €	2030
4. Royalties	5% of net sales	2.500.000,00 USD	2.300.000,00 €	2031
TOTAL		**3.000.000,00 USD**	**2.760.000,00 €**	

8.6. Profit and Loss

This statement provides the financial condition of the company and reveals the growth potential and financial strength. It is fundamental to analyse this statement, assuming that all payments and expenses take place as stated in previous sections. However, as appreciable in *Table 11* and *Table 12*, the utility expenses related to the use of a laboratory (for electricity, gas, other heating and cooking fuels, water, etc.) are added and taken into consideration in this statement. In *Table 11* and *Table 12*, the Profit and Loss statements

over the period from 2022 to 2031 are appreciable. Detailed information is available in Appendix 14.4 (Section 15.4.6).

Table 11: Profit and Loss statement (2022-2026)

	2022	2023	2024	2025	2026
Profits	**138.000,00 €**	**150.000,00 €**	**220.800,00 €**	**414.000,00 €**	**- €**
GRANT	- €	150.000,00 €	- €	- €	- €
Upfront Payment	82.800,00 €	- €	- €	- €	- €
License Fee	55.200,00 €	- €	- €	- €	- €
Milestone 1	- €	- €	220.800,00 €	414.000,00 €	- €
Milestone 2	- €	- €	- €	- €	- €
Milestone 3	- €	- €	- €	- €	- €
Milestone 4	- €	- €	- €	- €	- €
Exploitation Costs	**113.333,30 €**	**120.450,80 €**	**120.636,20 €**	**99.993,96 €**	**51.962,43 €**
HH.RR + taxes	39.000,00 €	41.617,50 €	41.802,90 €	41.993,86 €	43.962,43 €
Depreciation	54.333,30 €	58.833,30 €	58.833,30 €	58.000,10 €	8.000,00 €
Utility costs	20.000,00 €	20.000,00 €	20.000,00 €	- €	- €
EBITDA	**79.000,00 €**	**88.382,50 €**	**158.997,10 €**	**372.006,14 €**	**- 43.962,43 €**
EBIT	**24.666,70 €**	**29.549,20 €**	**100.163,80 €**	**314.006,04 €**	**- 51.962,43 €**
NET PROFIT	**18.500,03 €**	**22.161,90 €**	**75.122,85 €**	**235.504,53 €**	**- 51.962,43 €**

Table 12: Profit and Loss statements 2027-2031

	2027	2028	2029	2030	2031
Profits	**745.200,00 €**	**- €**	**- €**	**1.242.000,00 €**	**2.300.000,00 €**
GRANT	- €	- €	- €	- €	- €
Upfront Payment	- €	- €	- €	- €	- €
License Fee	- €	- €	- €	- €	- €
Milestone 1	- €	- €	- €	- €	- €
Milestone 2	745.200,00 €	- €	- €	- €	- €
Milestone 3	- €	- €	- €	1.242.000,00 €	- €
Milestone 4	- €	- €	- €	- €	2.300.000,00 €
Exploitation Costs	**49.165,02 €**	**46.234,16 €**	**48.402,58 €**	**48.623,96 €**	**50.903,14 €**
HH.RR + taxes	44.165,02 €	46.234,16 €	48.402,58 €	48.623,96 €	50.903,14 €
Depreciation	5.000,00 €	- €	- €	- €	
Utility costs	- €	- €	- €	- €	- €
EBITDA	**701.034,98 €**	**- 46.234,16 €**	**- 48.402,58 €**	**1.193.376,04 €**	**2.249.096,86 €**
EBIT	**696.034,98 €**	**- 46.234,16 €**	**- 48.402,58 €**	**1.193.376,04 €**	**2.249.096,86 €**
NET PROFIT	**522.026,24 €**	**- 46.234,16 €**	**- 48.402,58 €**	**895.032,03 €**	**1.686.822,64 €**

As it is appreciable in *Table 11* and *Table 12*, the indicators EBITDA (Earnings Before Interests, Taxes, Depreciation and Amortization) and EBIT (Earnings Before Interests and Taxes) are computed. These two metrics are useful for the computation of

profitability ratios and operation performance of the company further in this thesis. The formulas used to obtain such values are appreciable in *Equation 1* and *Equation 2.*

$$EBITDA = Net\ income + Interests + Tax + Depreciation + Amortization$$

Equation 1: EBITDA formula

$$EBIT = Net\ income + Interests + Tax$$

Equation 2: EBIT formula

8.7. Financial Indicators

The values obtained in previous sections are used to obtain three key indicators: the Total Income, the Net Profit and the Cash Flow. Detailed information on the computation of such indicators is available in Appendix 14.4 (Section 15.4.7). With these indicators, the financial situation of Nanotarg over the period 2022 to 2031 is estimated and represented in *Figure 10.*

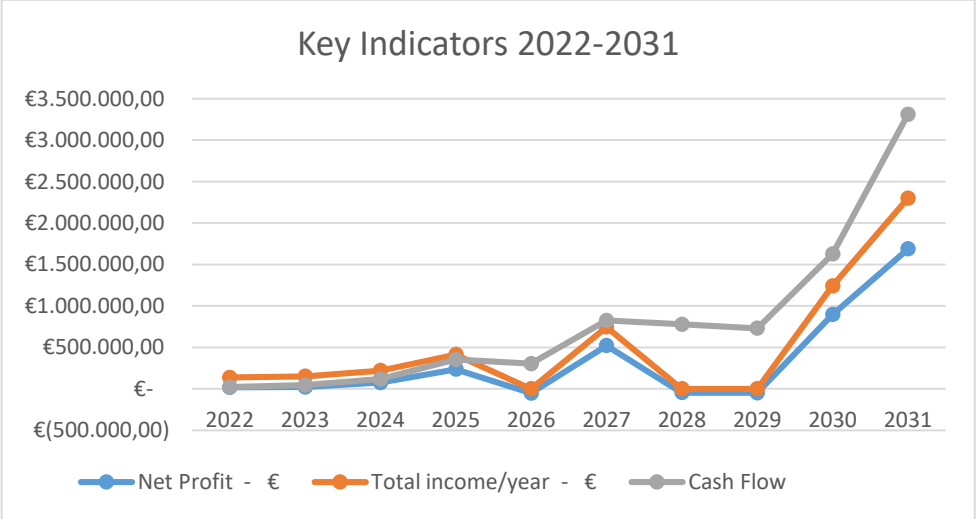


Figure 10: Evolution of Net Profit, Total Income and Cash Flow over the period 2022-2031

8.8. Ratios

Although financial indicators provide information about the financial situation of the company, they cannot asses the profitability or the solvency of a company. Hence, it is fundamental to rely on numerical measures of performance. For this reason, ratios and metrics have been obtained and are displayed in *Table 13* and *Table 14*. Detailed

information with reference to the acquisition of such ratios is available in Appendix 14.4 (Section 15.4.8).

Table 13: Financial Ratios (2022-2026)

	2022	2023	2024	2025	2026
ROE	24%	16%	27%	41%	-10%
ROI	10%	11%	29%	54%	-10%
EBTIDA/income	57%	59%	72%	90%	-
Gross Margin	18%	20%	45%	76%	-
Solvency	146%	209%	488%	4479%	10607%
Break-even point	113.333,30 €	120.450,80 €	120.636,20 €	99.993,96 €	51.962,43 €

Table 14: Financial Ratios (2027-2031)

	2027	2028	2029	2030	2031
ROE	50%	-5%	-5%	48%	48%
ROI	66%	-5%	-5%	64%	64%
EBTIDA/income	94%	-	-	96%	98%
Gross Margin	93%	-	-	96%	98%
Solvency	-	-	-	-	-
Break-even point	49.165,02 €	46.234,16 €	48.402,58 €	48.623,96 €	50.903,14 €

8.9. Financial Conclusions

Financial conclusions arise from the analysis and study of the data revealed in previous sections.

The financial indicators reveal in *Figure 9* a significant growth over the period from 2022 to 2031. With regards to the Total Income and Net Profit, they are especially related to the revenues obtained in each year. Hence, they depend tightly on the licensing agreement imbursements and the reward obtained from governmental grants in 2023. For this reason and despite of the total growth of these indicators over the period, sudden Income drops appear in 2026, 2028 and 2029, when no revenues are obtained according to the estimated license agreement appreciable in *Table 10.*

On the other hand, the Cash Flow indicator (in *Figure 9)* presents almost a constant climb over the period, which means that the liquidity of the company increases with years. A significant inclination at the end of the time interval is due to the high incomes related to milestones, royalties and lower depreciation costs.

In conclusion, the estimated financial situation of the company reveals an optimistic development. However, if the programmed milestones are not finally accomplished the company would receive no more revenues but should still have to afford depreciation and utility costs.

With regards to the profitability ratios ROE and ROI (*Table 13* and *Table 14)*, they fundamentally assess the profit obtained by the usage of capital. The company is estimated to have good and growing profitability ratios over the years when revenues are obtained, especially those when milestones are accomplished. On the other hand, the profitability ratios keep negative values when no incomes are obtained.

Concerning the Gross Margin and the EBITDA-to-sales ratio (*Table 13* and *Table 14*), the same behaviour is obtained. While they grow over the whole period, null values of such ratios appear those years when no revenues are received. Moreover, no investments appear to be planned from 2027 and hence, the profitability ratios over the period 2027 to 2031 could be especially inaccurate.

When it comes to the solvency ratio (*Table 13* and *Table 14*), it reveals a considerable increase over the period since, liabilities keep decreasing each year. Therefore, the company owns more than it owes. However, as mentioned, there is no investment planned from 2027 and hence, all the liabilities are depreciated. That is why no solvency ratios are available from 2027 to 2031.

Finally, it easy to conclude that Nanotarg is estimated to be financially profitable and solvent over the period from 2022-2031. However, a financial plan over approximately 10 years cannot be especially accurate. Firstly, it is very likely that the license will not reach the stated milestones and therefore, the income will be cut off at some point. Secondly, there is no clear investment plan in the long run and if revenues are cut-off there is no other possible source of income. For this reason, it is vital to keep evolving and constantly thinking about new approaches to obtain revenues, so that if this project cannot proceed, the continuity of the company could rely on other activities.

9. FUTURE GROWTH AND MARKET EXTENSION

In order to assess the potential future growth and market extension of the technology, an Ansoff Matrix will be used as planning technique [63].

Table 15: Ansoff matrix for Nanotarg

	Existing Products	New Products
New Markets		**Diversification:** Innovation towards other tumours. Targeting other tumours.
Existing Markets	**Market penetration:** Become gold standard therapy.	**Product development:** Innovation towards targeted diagnosis for PDAC**.** Using a contrast agent as a cargo.

As appreciable in *Table 15*, the platform could be further developed to explore new markets as a new product. In other words, the platform could be potentially used to target other tumours and hence, have a more diverse focus. On the other hand, Nanotarg could potentially use as *cargo* other compounds such as contrast agents. Therefore, it would become a totally different product, a tool for early diagnosis of PDAC.

These are different approaches that should be further studied to ensure the proper evolution of the company.

10. CONCLUSION

10.1. Business Plan conclusion

The business plan mentioned in previous sections is certainly attached to a very high degree of uncertainty and will undoubtedly be modified if the project manages through this hard and difficult path that is entrepreneurship. However, the potential is huge and it is vital to always have a plan as accurate as possible. That was the main goal of this thesis, to consider some of the factors affecting Nanotarg and provide guidelines.

10.2. General conclusion

High aggressiveness, poor diagnosis, ineffective treatments and an upward trend of the global pancreatic cancer market size manifest strongly the urgent need to develop effective approaches to manage this pathology. Within the scope of this thesis I noticed

that it is certainly a problematic addressed by many of the top pharmaceutical companies around the world. Fundamentally, pharmaceutical companies are constantly performing technological surveillance to spot any potential compound that could lead to better results or performance in a certain pathology. Nonetheless, it is not a secret that big companies have the focus on revenues more than on people, despite of the huge efforts on pretending to care for human life.

For this reason, I have the strong belief that technology transfer should play an important role to ensure that valuable knowledge can lead to new treatments and it is delivered to society. It is an activity becoming more and more popular among universities and research centres, but it needs to be considered as a core feature of such institutions to finally obtain a knowledge valorisation environment and culture. Emerging companies (spin-off) born from these institutions have to focus on dynamism and use revenues to constantly find potential new solutions. Still, it is fundamental that governmental organizations understand and support this activity and create initiatives to enhance it.

In conclusion, technology valorisation is an extremely important activity that makes a major contribution to society. Nanotarg, is an example of many other projects.

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14. APPENDICES

14.1. Opportunity Analysis

Although each case of PDAC is different and clinicians use independent medical judgement in the context of individual clinical circumstances to determine patients' treatment, guidelines and consensus exist [10]. According to the 2020 National Comprehensive Cancer Network (NCCN) Pancreatic Adenocarcinoma Guidelines [10] the preferred treatment regimens for the different stages of PDAC appear in *Tables 16-20.* As appreciable, PDAC is classified within resectable and non-resectable tumours. On the one hand, resectable tumours can be treated with adjuvant or neo-adjuvant treatments. On the other hand, non-resectable PDAC is classified among Locally Advanced Pancreatic Cancer (LAPC) or metastatic. However, the combination of Albumin-Bound Paclitaxel and Gemcitabine is used in the vast majority of the cases as a preferred regime.

Table 16: Neoadjuvant Chemotherapy preferred regimens for Resectable PDAC [10].

REGIMEN	DOSING
Neoadjuvant Chemotherapy (Resectable/Borderline Resectable Disease)[a]	
Preferred Regimens	
FOLFIRINOX[2,b,c]	**Day 1:** Oxaliplatin 85mg/m² IV over 2 hours **Day 1:** Irinotecan 180mg/m² IV over 90 minutes **Day 1:** Leucovorin 400mg/m² IV over 90 minutes, **followed by:** **Day 1:** Fluorouracil 400mg/m² IV push, **followed by:** **Days 1-2:** Fluorouracil 1,200mg/m² IV continuous infusion over 24 hours (2,400mg/m² IV over 46 hours). Repeat cycle every 2 weeks for 4-12 cycles.
Modified FOLFIRINOX[2,b,c]	**Day 1:** Oxaliplatin 85mg/m² IV over 2 hours, **followed by:** **Day 1:** Leucovorin 400mg/m² IV over 2 hours, **followed (after 30 minutes) by:** **Day 1:** Irinotecan 135mg/m² IV over 90 minutes, **followed by:** **Day 1:** Fluorouracil 300mg/m² IV bolus, **followed by:** **Days 1-2:** Fluorouracil 1,200mg/m² IV continuous infusion over 24 hours (2,400mg/m² IV over 46 hours). Repeat cycle every 2 weeks for 4-12 cycles.
Gemcitabine + Albumin-Bound Paclitaxel[4,b,d]	**Days 1,8,15:** Albumin-bound Paclitaxel 125mg/m² IV over 30 minutes **Days 1,8,15:** Gemcitabine 1,000mg/m² IV over 30 minutes. Repeat cycle every 4 weeks for 2-6 cycles.

Table 17: Adjuvant Chemotherapy preferred regimens for Resectable PDAC [10].

REGIMEN	DOSING
Adjuvant Chemotherapy	
Preferred Regimens	
Modified FOLFIRINOX (Category 1)[3,c]	**Day 1:** Oxaliplatin 85mg/m² IV over 2 hours, **followed by:** **Day 1:** Leucovorin 400mg/m² IV over 2 hours, **followed (after 30 minutes) by:** **Day 1:** Irinotecan 135mg/m² IV over 90 minutes, **followed by:** **Day 1:** Fluorouracil 300mg/m² IV bolus, **followed by:** **Days 1-2:** Fluorouracil 1,200mg/m² IV continuous infusion over 24 hours (2,400mg/m² IV over 46 hours). Repeat cycle every 2 weeks for 4-12 cycles.
Gemcitabine + Capecitabine (Category 1)[7]	**Days 1,8,15:** Gemcitabine 1000mg/m² IV **Days 1-21:** Capecitabine 830mg/m² orally twice daily Repeat cycle every 4 weeks for 6 cycles.

Table 18: First-line Chemotherapy preferred regimens for LAPC PDAC [10].

REGIMEN	DOSING
First-Line Chemotherapy for Locally Advanced Disease and Good Performance Status	
Preferred Regimens	
FOLFIRINOX[2,c,g,h]	**Day 1:** Oxaliplatin 85mg/m² IV over 2 hours **Day 1:** Irinotecan 180mg/m² IV over 90 minutes **Day 1:** Leucovorin 400mg/m² IV over 90 minutes, **followed by:** **Day 1:** Fluorouracil 400mg/m² IV push, **followed by:** **Days 1-2:** Fluorouracil 1,200mg/m² IV continuous infusion over 24 hours (2,400mg/m² IV over 46 hours). Repeat cycle every 2 weeks for 4-12 cycles.
Modified FOLFIRINOX[3,c,g,h]	**Day 1:** Oxaliplatin 85mg/m² IV over 2 hours, **followed by:** **Day 1:** Leucovorin 400mg/m² IV over 2 hours, **followed (after 30 minutes) by:** **Day 1:** Irinotecan 135mg/m² IV over 90 minutes, **followed by:** **Day 1:** Fluorouracil 300mg/m² IV bolus, **followed by:** **Days 1-2:** Fluorouracil 1,200mg/m² IV continuous infusion over 24 hours (2,400mg/m² IV over 46 hours). Repeat cycle every 2 weeks for 4-12 cycles.
Gemcitabine + Albumin-Bound Paclitaxel[4,d,h]	**Days 1,8,15:** Albumin-bound Paclitaxel 125mg/m² IV over 30 minutes **Days 1,8,15:** Gemcitabine 1,000mg/m² IV over 30 minutes. Repeat cycle every 4 weeks for 2-6 cycles.

Table 19: First-line Chemotherapy preferred regimens for Metastatic PDAC [10].

REGIMEN	DOSING
First-Line Chemotherapy for Metastatic Disease and Good Performance Status	
Preferred Regimens	
FOLFIRINOX (Category 1)[2,c,g]	**Day 1:** Oxaliplatin 85mg/m² IV over 2 hours **Day 1:** Irinotecan 180mg/m² IV over 90 minutes **Day 1:** Leucovorin 400mg/m² IV over 90 minutes, **followed by:** **Day 1:** Fluorouracil 400mg/m² IV push, **followed by:** **Days 1-2:** Fluorouracil 1,200mg/m² IV continuous infusion over 24 hours (2,400mg/m² IV over 46 hours). Repeat cycle every 2 weeks.
Modified FOLFIRINOX[3,c,g]	**Day 1:** Oxaliplatin 85mg/m² IV over 2 hours, **followed by:** **Day 1:** Leucovorin 400mg/m² IV over 2 hours, **followed (after 30 minutes) by:** **Day 1:** Irinotecan 135mg/m² IV over 90 minutes, **followed by:** **Days 1:** Fluorouracil 300mg/m² IV bolus, **followed by:** **Days 1-2:** Fluorouracil 1,200mg/m² IV continuous infusion over 24 hours (2,400mg/m² IV over 46 hours). Repeat cycle every 2 weeks.
Gemcitabine + Albumin-Bound Paclitaxel (Category 1)[4,d]	**Days 1,8,15:** Albumin-bound Paclitaxel 125mg/m² IV over 30 minutes **Days 1,8,15:** Gemcitabine 1,000mg/m² IV over 30 minutes. Repeat cycle every 4 weeks.

Table 20: Second-line Chemotherapy preferred regimens for LAPC/Metastatic PDAC [10]

REGIMEN	DOSING
Second-Line Therapy for Locally Advanced/Metastatic Disease and Therapy for Recurrent Disease: Good Performance Status	
Other Recommended Regimens (if prior gemcitabine-based therapy)	
Capecitabine[15]	**Days 1-14:** Capecitabine 1,000mg/m² orally twice daily. Repeat cycle every 3 weeks.
CapeOX[16,36]	**Day 1:** Oxaliplatin 110-130mg/m² IV over 2 hours **Days 1-14:** Capecitabine 750-1,000mg/m² orally twice daily. Repeat cycle every 3 weeks.
Fluorouracil, Continuous Infusion[9]	**Days 1-28**: Fluorouracil 250mg/m² IV continuous infusion over 24 hours. Repeat cycle every 42 days.
Fluorouracil + Leucovorin + Liposomal Irinotecan (Category 1 for metastatic disease)[37,38,k]	**Day 1:** Liposomal Irinotecan 80mg/m² IV (equivalent to 70mg/m² IV Irinotecan in free base), **followed by:** **Day 1:** Leucovorin 400mg/m² IV, **followed by:** **Days 1-2:** Fluorouracil 1,200mg/m² IV continuous infusion (2,400mg/m² over 46 hours). Repeat cycle every 2 weeks.
Fluorouracil + Leucovorin + Oxaliplatin [OFF][17]	**Days 1,8,15,22:** Leucovorin 200mg/m² IV over 2 hours **Days 8,22:** Oxaliplatin 85mg/m² IV over 2 hours, **followed by:** **Days 1,8,15,22:** Fluororuacil 2,000mg/m² IV continuous infusion over 24 hours. Repeat cycle every 42 days.
FOLFIRI[30,31]	**Day 1:** Irinotecan 180mg/m² IV over 90 minutes, **with:** **Day 1:** Leucovorin 400mg/m² IV over 2 hours, **followed by:** **Day 1:** Fluorouracil 400mg/m² IV push, **followed by:** **Days 1-2:** Fluorouracil 1,200mg/m² IV every 24 hours (2,400mg/m² IV over 46 hours). Repeat cycle every 2 weeks.
Second-Line Therapy for Locally Advanced/Metastatic Disease and Therapy for Recurrent Disease: Good Performance Status (continued)	
Other Recommended Regimens (if prior gemcitabine-based therapy) (continued)	
FOLFOX[32]	**Day 1:** Oxaliplatin 100mg/m² IV over 2 hours **Day 1:** Leucovorin 400mg/m² IV over 2 hours, **followed by:** **Day 1:** Fluorouracil 400mg/m² IV push, **followed by:** **Days 1-2:** Fluorouracil 1,500mg/m² IV continuous infusion over 24 hours (3,000mg/m² IV over 46 hours) Repeat cycle every 2 weeks.
FOLFIRINOX[2,c]	**Day 1:** Oxaliplatin 85mg/m² IV over 2 hours **Day 1:** Irinotecan 180mg/m² IV over 90 minutes **Day 1:** Leucovorin 400mg/m² IV over 90 minutes, **followed by:** **Day 1:** Fluorouracil 400mg/m² IV push, **followed by:** **Days 1-2:** Fluorouracil 1,200mg/m² IV continuous infusion over 24 hours (2,400mg/m² IV over 46 hours). Repeat cycle every 2 weeks.
Modified FOLFIRINOX[3,c]	**Day 1:** Oxaliplatin 85mg/m² IV over 2 hours, **followed by:** **Day 1:** Leucovorin 400mg/m² IV over 2 hours, **followed (after 30 minutes) by:** **Day 1:** Irinotecan 135mg/m² IV over 90 minutes, **followed by:** **Day 1:** Fluorouracil 300mg/m² IV bolus, **followed by:** **Days 1-2:** Fluorouracil 1,200mg/m² IV continuous infusion over 24 hours (2,400mg/m² IV over 46 hours). Repeat cycle every 2 weeks.
Other Recommended Regimens (if prior fluoropyrimidine-based therapy)	
Fluorouracil + Leucovorin + Liposomal Irinotecan (if no prior Irinotecan)[37,38,k]	**Day 1:** Liposomal Irinotecan 80mg/m² IV (equivalent to 70mg/m² IV Irinotecan in free base), **followed by:** **Day 1:** Leucovorin 400mg/m² IV, **followed by:** **Days 1-2:** Fluorouracil 1,200mg/m² IV continuous infusion (2,400mg/m² over 46 hours). Repeat cycle every 2 weeks.
Gemcitabine[18,19]	**Days 1,8,15:** Gemcitabine 1,000mg/m² IV over 30 minutes. Repeat cycle every 4 weeks.
Gemcitabine + Albumin-Bound Paclitaxel[4,d]	**Days 1,8,15:** Albumin-bound Paclitaxel 125mg/m² IV over 30 minutes **Days 1,8,15:** Gemcitabine 1,000mg/m² IV over 30 minutes. Repeat cycle every 4 weeks.
Gemcitabine + Cisplatin (only for known *BRCA1/2* or *PALB2* mutations)[13,14,e]	**Days 1,15:** Cisplatin 50mg/m² IV over 60 minutes **Days 1,15:** Gemcitabine 1,000mg/m² IV over 30 minutes. Repeat cycle every 4 weeks. **OR** **Days 1,8,15,29,36,43:** Cisplatin 25mg/m² IV over 60 minutes **Days 1,8,15,29,36,43:** Gemcitabine 1000mg/m² IV over 30 minutes. Administer for one 56-day cycle, **followed by:** **Days 1,8,15:** Cisplatin 25mg/m² over 60 minutes **Days 1,8,15:** Gemcitabine 1000mg/m² over 30 minutes. Repeat cycle every 4 weeks.
Gemcitabine + Erlotinib[21]	**Days 1,8,15,22,29,36,43:** Gemcitabine 1,000mg/m² IV over 30 minutes **Days 1-56:** Erlotinib 100mg orally daily. Administer for one 56-day cycle, **followed by:** **Days 1,8,15 (subsequent cycles):** Gemcitabine 1,000mg/m² IV over 30 minutes **Days 1-28:** Erlotinib 100mg orally daily. Repeat cycle every 4 weeks.

14.2. PESTEL ANALYSIS

14.2.1. Political factors

Politics are related to the expansion of the welfare state and have undoubtedly an impact on the delivery of health to citizens [13]. In the world, there are different typologies of health care systems or welfare regimens and this fact is extremely related to their political organization. More concretely, the treatment of orphan or rare disease within health care systems is especially controversial and may be attached to certain ethical dilemmas due to monetary concerns [14]. The cost of developing any orphan drug is very high, however due to the rarity of the disease, the cost cannot be recovered by the sales of the product. For this reason, the implantation of such treatments depends strongly on the economic actions of governments [64].

A clear example of this is Onivyde (irinotecan). This effective drug aiming to treat PDAC is not currently available in the Spanish health care system since the Ministry of Health decided not to finance it publicly [15]. Probably, this decision derives form monetary or economic concerns. However, this drug is used in France's health care system.

This makes evident that depending on the political organizations and decisions a drug may not be able to reach a certain market.

14.2.2. Economic factors

The global pharmaceutical industry is large and profitable. Pharmaceutical industry market made great progress over the last decade and generated 1.2$ trillion revenues in 2018 [65]. Hence, pharmaceutical industry is a key asset for the world's economy and is a top performing high-technology sector.

Globally, the sector is dominated by North America and Europe (known as Big Pharma) who are still the largest global markets for pharmaceutical industry, accounting for 48.1% and 22.2% of the sales in 2017 respectively [66] [67]. However, emerging markets (Japan, China, Brazil, Venezuela, India…) are expected to play an important role in the growth of the industry [68].

14.2.2.1. Pancreatic Cancer industry and trends

Oncology is the area with the largest proportion of clinical development spending 40% of total pharmaceutical pipeline expenditure [69]. The global cancer therapeutics market size was valued at $98,900 million in 2018 [70], and the global market size of pancreatic cancer was around USD $1,904.20 [71]. Approximately 1.93% of the global cancer market derives from pancreatic cancer.

Pancreatic cancer global market size is estimated to value $4,728.19 million by 2026 [72] and is expected to grow at a CAGR (Compound Annual Growth Rate) of 8.1% during the forecast period of 2017-2023 [73].

14.2.2.2. Cancer therapy market

The current research lines and marketed drugs aiming to treat PDAC are mainly based on immunotherapy, targeted therapy and chemotherapy. The revenue shares (%) by therapy type in 2019 are appreciable in *Figure 11* [74].

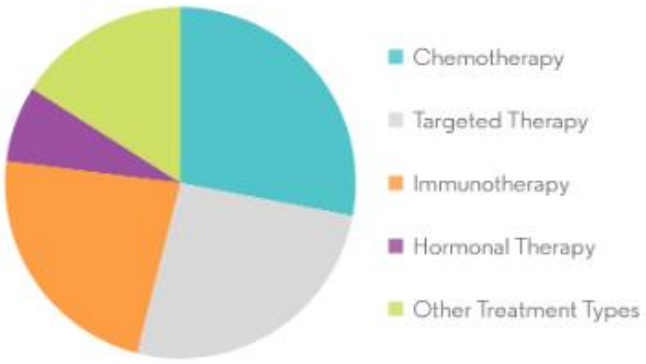

Figure 11: Cancer Therapy Market: Revenue Share (%) by therapy type [74]

14.2.2.3. Key players and industry

Currently, many pharma companies are either working on clinical trials for new potential drugs and treatments or already have a marketed drug for PDAC. According to tables appreciable in Appendix 14.3, the top companies approaching PDAC are: Elli Lilly, Merck and Co, Roche Holding AG and Celgene. These companies all have a commercial drug and are currently on clinical trials to approach PDAC. The annual revenues of this companies are very high and are globally considered the top companies in pharmaceutical

industry. For this reason, it is easy to conclude that those companies who are approaching successfully PDAC are very powerful and important

14.2.2.4. COVID-19 situation

Due to the COVID-19 crisis the world economy is suffering a recession. In other words, the pandemic has caused severe repercussions in the economies all over the words. So, even thought that the pancreatic cancer industry seems to be growing, the world economy is in recession [75]. However, as it is a sanitary crisis, it is reasonable to think that investment on science and innovation is about to increase.

14.2.3. Social factors

14.2.3.1. Emerging sectors

Emerging markets represent an opportunity for pharmaceutical industry. Leading economies of emerging regions are known as the BRIC (Brazil, Russia, Indi and China) and the MIST (Mexico, Indonesia, South Korea and Turkey) [76]. Life expectancy, longevity and prosperity are growing and hence, a shift in the disease patterns is occurring. This means that those regions present high growth potential, owing to rise in cancer awareness and increase the investment [77].

14.2.3.2. Population growth rate

Human population growth amounts to 83 million annually or 1.1% per year. It is expected to keep growing [78].

14.2.3.3. Age distribution

Life expectancy increased 5.5 points from 2000 to 2016 [79]. Aging population brings a wide range of opportunities to this pharma sector since it is known that the risk of developing pancreatic cancer increases with age. The highest incidence is reported over 70 years and the mortality rate of pancreatic cancer in both males and females increases with age, and almost 90% of all deaths occur after the age of 55 year [4]. The pathology could become more popular in the future.

14.2.3.4. Tobacco use

There are over one thousand million smokers worldwide and it is the most important environmental factor for pancreatic cancer. The risk of getting pancreatic cancer is about twice as high among smokers. The prevalence of smoking has declined in developed countries, but it remains high in other regions and appears to be increasing among women in developed countries [4]. Moreover, in India and China there are more smokers than the total population of Europe.

14.2.3.5. Obesity

Obesity is associated with increased pancreatic cancer risk, more concretely, obese people are 20% more likely to develop PDAC [4] [80].

14.2.3.6. Ethnicity and incidence

Different studies reported differences in the incidence of pancreatic cancer between races. The incidence appears to be the lowest for Asian and Pacific Islanders and the highest for Caucasians and African-Americans [81].

In 2018, the age-standardized rate (ASR) incidence was highest in Europe (7.7 per 100,000 people) and North America (7.6 per 100,000 people), followed by Oceania (6.4 per 100,000 people). The lowest rate was observed in Africa with an estimated incidence of 2.2 per 100,000 people [4].

14.2.4. Technological factors

14.2.4.1. Other treatments approaches

Different approaches are being considered when addressing PDAC. Concerning chemotherapy, many drugs addressing PDAC are in the market nowadays and many other are going through clinical trials. However, with reference to immunotherapy and targeted therapy, there are few or no PDAC marketed drugs although clinical trials in phase III exist. See Appendix 14.3 for detailed information.

14.2.4.2. Nanotarg key feature: Multifunctional platform

Nanotarg is a multifunctional platform with many potential uses. It is crucial to consider that this specific targeting may be used with different purposes in the future and therefore,

a properly IP strategy must be considered. Although the current goal is to address PDAC using a chemotherapy agent nab-paclitaxel, the specific targeting may be used for different purposes, such as using other drug types or other molecules like contrast agents.

14.2.5. Environmental factors

14.2.5.1. Environmental impact of the platform

Nanotechnology offers unique properties that differ from traditional ones and possesses different safety concerns. Environmental impact of nanotechnology is on debate regarding to the impact on organisms and ecosystems. It is considered a nowadays challenge because nanowaste may reach effluents, float in the air, penetrate plant cells, etc. causing nanopollution with unknown effects [82]. There is also a problematic associated to the contamination of soil and the effect on the flora and fauna. For this reason, fabrication, distribution, application of nanoparticles must be strongly assessed.

In this case, with regards to Nanotarg, it is a biodegradable platform, which means that the platform can be broken down by the action of naturally occurring microorganisms [83].

Furthermore, all the elements used to accomplish the final form of the platform are classified as GRASE (Generally Recognized As Safe and Effective) by the FDA. Still, according to the FDA, it is a requirement to submit an Environmental Assessment when requesting the agency action on a drug [84].

14.2.5.2. Environmental impact of nab-paclitaxel

The environmental factors associated to the manufacturing of nab-paclitaxel do not need to be exhaustively considered as this compound is already in the market and the potentially damaging effects have already been considered. However, according to Abraxane's Safety Data Sheet by Celgene [85], the environmental characteristics of the substance have not been fully investigated and the releases of such material to the environment should be avoided. Moreover, all wastes resulting from clean-ups need to be brought to municipal wastewater treatment facilities in an environmentally safe manner [86]. Finally, the substance Abraxane is not considered an environmental hazard or a marine pollutant.

14.2.6. Legal factors

FDA has recognized that because development of nanotechnology-based drugs is still in its infancy, there are no established standards for the study or regulatory evaluation of these products. FDA has no regulatory definitions of "nanotechnology", "nanomaterial", "nanoscale", etc. [87]. Therefore, FDA considers the characteristics of the product and its safety and effectiveness for its use [88].

Thus, many drugs addressing PDAC are designated as orphan drugs. Furthermore, this designation allows manufacturers to qualify for various incentives, including tax credits for qualified clinical trials and 7 years of market exclusivity [89]. For this reason, the orphan drug designation is a suitable regulatory option that need to be considered.

14.3. Market Analysis

14.3.1. Chemotherapy: Marketed drugs and clinical trials for PDAC

Table 21: Marketed chemotherapy compounds [90] [91] [92] [93] [94] [95]

Commercial Name	Molecule/Drug	Pharma Company
Gemzar	gemcitabine	Eli Lilly and Company
Abraxane	nab-paclitaxel	Celgene Corporation
Adrucil	5-FU (fluorouracil)	Teva Pharmaceuticals
Camptosar	irinotecan	Pfizer Inc.
Eloxatin	oxaliplatin	Sanofi
Xeloda	capecitabine	Roche Holding AG

Table 22: Clinical trial phase III chemotherapy compounds [96] [97] [98] [99] [100]

Commercial Name	Molecule/Drug	Pharma company
Napabucasin	2-acetylnaphtho[2,3-b] furan-4,9-dione	Boston Biomedical
Doranidazole	2-acetylbenzo[f][1] benzofuran-4,9-dione	Pola Pharma
Acelarin	gemcitabine-phosphoramidate NUC-1031	NuCana
Glufosfamide	glucosylifostamide mustard	Eleison Pharmaceuticals
CPI-613	devimistat	Raphael Pharmaceuticals

Table 23: Clinical trial phase II chemotherapy compounds [101] [102]

Commercial Name	Molecule	Pharma company
Rubraca	rucaparib	Clovis Oncology
Unknown	AZD1775	AstraZeneca

14.3.2. Immunotherapy: Marketed drugs and clinical trials for PDAC

Table 24: Marketed immunotherapy compounds [103]

Commercial Name	Molecule	Pharma company
Keytruda	GSK's inhibitor (OX40 agonist GSK3174998)	Merck and Co.

Table 25: Clinical trial phase III immunotherapy compounds [104]

Commercial Name	Molecule	Pharma company
Unknown	mastinib	AB Science

Table 26: Clinical trial phase II immunotherapy compounds [105] [106]

Commercial Name	Molecule	Pharma company
Unknown	istiratumab	Merrimack Pharmaceuticals
Unknown	OBI-999	OBI Pharma

Table 27: Clinical trial phase I immunotherapy compounds [107] [108] [109] [110]

Commercial Name	Molecule	Pharma company
Latruvo	orlaratumab	Eli Lilly and Company
Unknown	sofitzumab vedotin	Roche Holding AG
Unknown	CD40 antibody APX005M	Apexigen
Unknown	MRx0518	ChiMed

14.3.3. Targeted therapy: Marketed drugs and clinical trials for PDAC

Table 28: Marketed targeted therapy compounds [29] [30]

Commercial Name	Molecule	Pharma company
Lynparza	olaparib	Merck and Co.
Tarcevas	erlotinib	Roche Holding AG

Table 29: Clinical trial phase III targeted therapy compounds [34]

Commercial Name	Molecule	Pharma company
Eryaspase	L-asparaginase encapsulated inside donor-derived red blood cells	Erytech Pharma

Table 30: Clinical trial phase II targeted therapy compounds [31] [32]

Commercial Name	Molecule	Pharma company
Nanopac	Sub-micron paclitaxel	NanOlogy
Unknown	aldoxorubicin	NantCell

Table 31: Clinical trial phase I targeted therapy compounds [111]

Commercial Name	Molecule	Pharma company
Unknown	MultiTAA T cell therapy	Marker Therapeutics

14.4. Financial Plan

In this Appendix, financial concepts and detailed information about Nanotarg's financial plan are provided.

14.4.1. Starting Balance Sheet

A balance sheet is a statement that assesses the financial situation and position of a company in a given time [112]. It reports the assets and liabilities of a business.

- Assets: Anything owned by the business or owed to the business. There are different types of assets. Noncurrent assets refer to assets whose useful life is more than one year and can be considered tangible or intangible. The first exist physically and the second have a subjective value [113]. On the other hand, current assets refers to bank cash, value added tax (VAT) and those assets who rapidly turn into cash. [113].

- Liabilities: Debts a business owns or the money owed by the business due to be paid to its creditors [113], including the VAT.

In *Table 6*, the estimated Balance Sheet of the company Nanotarg in 2022 (just after constitution) is appreciable. The assets of Nanotarg have a total value of 21.025 €. They consist in equipment (software and hardware), a web page, the Intellectual Property of the 1st patent, an initial amount of treasury of 3000€ and the VAT associated to those assets. With regards to liabilities, it is easy to see that all the assets owned by the company need to be paid to creditors except the initial treasury, which is known as the equity of the company. Such concept derives from *Equation 3*.

$$Assets = Liabilities + Equity$$

Equation 3: Assets, Liabilities and Equity relation

14.4.2. Investment

Investment is a crucial part of a proper financial plan. It is fundamental to ensure the proper development of a company and it is a strategy that will help a business to meet long and short term goals [114]. As appreciable in *Table 7*, once a license agreement is reached in 2022, two initial investments appear. They refer to the second IP protection, a second patent of the platform encapsulating paclitaxel (the product the company aims to license), and constitution expenses, to constitute the spin-off company. Secondly, a huge amount of money will be invested over the period 2022-2025 on R&D activities, necessary to carry out preclinical studies. Finally, investment on marketing activities for the promotion and dissemination of the company will take place over 2023-2027.

14.4.3. Depreciation

The cost of the assets (tangible and intangible) and the investment needs to be depreciated over the years. Depreciation helps a company to earn revenue from a certain asset/investment while still paying a part of its cost each year [115]. In *Table 32*, the depreciation of the assets and the investment is appreciable. As it is an estimation, it is assumed that all assets and investments will be depreciated by 2028 and thus, no depreciation cost appears from 2028 to 2031. The depreciation values need to be understood as part of the costs of the company.

Table 32: Depreciation of assets and investment

Noncurrent assets				Repayment Installment					
Fixed assets		**Rate**	**Years**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**
Equipment	1.500,00 €	33,33%	3	500,00 €	500,00 €	500,00 €	- €	- €	- €
Intangible assets									
Web page	1.000,00 €	33,33%	3	333,30 €	333,30 €	333,30 €	0,10 €	- €	- €
Intellecutal Property 1	15.000,00 €	20%	5	3.000,00 €	3.000,00 €	3.000,00 €	3.000,00 €	3.000,00 €	- €
Intellectual Property 2	15.000,00 €	20%	5		3.000,00 €	3.000,00 €	3.000,00 €	3.000,00 €	3.000,00 €
R&D Activities	200.000,00 €	25%	4	50.000,00 €	50.000,00 €	50.000,00 €	50.000,00 €	- €	
Constitution expenses	500,00 €	100%	1	500,00 €	- €	- €	- €	- €	
Marketing Activities	10.000,00 €	20%	5	- €	2.000,00 €	2.000,00 €	2.000,00 €	2.000,00 €	2.000,00 €
				54.333,30 €	**58.833,30 €**	**58.833,30 €**	**58.000,10 €**	**8.000,00 €**	**5.000,00 €**

14.4.4. Human Resources

As any other company, there are costs associated to the employees' salaries. However, it is not so easy in this particular case. This is due to the fact that Nanotarg is a spin-off company and those people aimed to be "employed" by the company are researchers at UPF. Considering the legal policy from UPF, anyone working in the university is exclusively devoted to it and cannot work for any other company. This means that Nanotarg would need to outsource or subcontract a certain research group from UPF, so that it would be legal to "employ" those researchers. In *Tables 32-41* the HR estimated costs associated to Nanotarg entity are available. As it is appreciable, the Personal Income Tax (PIT) and the Social Security (SS) taxes for both the employees or partners and the company are taken into consideration. More concretely, the percentage of PIT and SS is obtained from Pérez Silvestre, V. (2013). "Plan financiero EOI". EOI Escuela de Negocios [58].

Table 33: HR expenses in 2022

	% Variation	Annual Salary	PIT	SS tax (employee)	Net Annual Salary	SS tax (partners)	SS tax (company)	Total cost
Partners								
Partner 1	- €	- €	10%	0%	- €	3.000,00 €	0%	3.000,00 €
Partner 2	- €	- €	10%	0%	- €	3.000,00 €	0%	3.000,00 €
Employees								
Postdoc	0%	25.000,00 €	17%	6,40%	19.150,00 €		32%	33.000,00 €
								39.000,00 €

Table 34: HR expenses in 2023

	% Variation	Annual Salary	PIT	SS tax (employee)	Net Annual Salary	SS tax (partners)	SS tax (company)	Total cost
Partners								
Partner 1	- €	- €	10%	0%	- €	3.090,00 €	0%	3.090,00 €
Partner 2	- €	- €	10%	0%	- €	3.090,00 €	0%	3.090,00 €
Employees								
Postdoc	5%	26.250,00 €	17%	3,40%	20.895,00 €		35%	35.437,50 €
								41.617,50 €

Table 35: HR expenses in 2024

	% Variation	Annual Salary	PIT	SS tax (employee)	Net Annual Salary	SS tax (partners)	SS tax (company)	Total cost
Partners								
Partner 1	- €	- €	10%	0%	- €	3.182,70 €	0%	3.182,70 €
Partner 2	- €	- €	10%	0%	- €	3.182,70 €	0%	3.182,70 €
Employees								
Postdoc	0%	26.250,00 €	17%	3,40%	20.895,00 €		35%	35.437,50 €
								41.802,90 €

Table 36: HR expenses in 2025

	% Variation	Annual Salary	PIT	SS tax (employee)	Net Annual Salary	SS tax (partners)	SS tax (company)	Total cost
Partners								
Partner 1	- €	- €	10%	0%	- €	3.278,18 €	0%	3.278,18 €
Partner 2	- €	- €	10%	0%	- €	3.278,18 €	0%	3.278,18 €
Employees								
Postdoc	0%	26.250,00 €	17%	3,40%	20.895,00 €		35%	35.437,50 €
								41.993,86 €

Table 37: HR expenses in 2026

	% Variation	Annual Salary	PIT	SS tax (employee)	Net Annual Salary	SS tax (partners)	SS tax (company)	Total cost
Partners								
Partner 1	- €	- €	10%	0%	- €	3.376,53 €	0%	3.376,53 €
Partner 2	- €	- €	10%	0%	- €	3.376,53 €	0%	3.376,53 €
Employees								
Postdoc	5%	27.562,50 €	17%	3,40%	21.939,75 €		35%	37.209,38 €
								43.962,43 €

Table 38: HR expenses in 2027

	% Variation	Annual Salary	PIT	SS tax (employee)	Net Annual Salary	SS tax (partners)	SS tax (company)	Total cost
Partners								
Partner 1	- €	- €	10%	0%	- €	3.477,82 €	0%	3.477,82 €
Partner 2	- €	- €	10%	0%	- €	3.477,82 €	0%	3.477,82 €
Employees								
Postdoc	0%	27.562,50 €	17%	3,40%	21.939,75 €		35%	37.209,38 €
								44.165,02 €

Table 39: HR expenses in 2028

	% Variation	Annual Salary	PIT	SS tax (employee)	Net Annual Salary	SS tax (partners)	SS tax (company)	Total cost
Partners								
Partner 1	- €	- €	10%	0%	- €	3.582,16 €	0%	3.582,16 €
Partner 2	- €	- €	10%	0%	- €	3.582,16 €	0%	3.582,16 €
Employees								
Postdoc	5%	28.940,63 €	17%	3,40%	23.036,74 €		35%	39.069,84 €
								46.234,16 €

Table 40: HR expenses in 2029

	% Variation	Annual Salary	PIT	SS tax (employee)	Net Annual Salary	SS tax (partners)	SS tax (company)	Total cost
Partners								
Partner 1	- €	- €	10%	0%	- €	3.689,62 €	0%	3.689,62 €
Partner 2	- €	- €	10%	0%	- €	3.689,62 €	0%	3.689,62 €
Employees								
Postdoc	5%	30.387,66 €	17%	3,40%	24.188,57 €		35%	41.023,34 €
								48.402,58 €

Table 41: HR expenses in 2030

	% Variation	Annual Salary	PIT	SS tax (employee)	Net Annual Salary	SS tax (partners)	SS tax (company)	Total cost
Partners								
Partner 1	- €	- €	10%	0%	- €	3.800,31 €	0%	3.800,31 €
Partner 2	- €	- €	10%	0%	- €	3.800,31 €	0%	3.800,31 €
Employees								
Postdoc	0%	30.387,66 €	17%	3,40%	24.188,57 €		35%	41.023,34 €
								48.623,96 €

Table 42: HR expenses in 2031

	% Variation	Annual Salary	PIT	SS tax (employee)	Net Annual Salary	SS tax (partners)	SS tax (company)	Total cost
Partners								
Partner 1	- €	- €	10%	0%	- €	3.914,32 €	0%	3.914,32 €
Partner 2	- €	- €	10%	0%	- €	3.914,32 €	0%	3.914,32 €
Employees								
Postdoc	5%	31.907,04 €	17%	3,40%	25.398,00 €		35%	43.074,50 €
								50.903,14 €

14.4.5. License agreement

A license agreement is a contract between a licensor and the licensee. Usually, the licensor (in this case, Nanotarg) grants to the licensee (Celgene) the right to use a patented technology [116] under certain conditions and payments. Considering data obtained from real license agreements [46][47], between pharma and research groups provided by the Global Data Intelligence Center, it is reasonable to think that a license agreement between Nanotarg and Celgene could potentially consist in a total deal of 3 USD million and include the different imbursements appreciable in *Table 10.* Furthermore, the estimated monetary quantities associated to the different payments have been selected and estimated considering the same proportions of such mentioned license agreements provided by Global Data Intelligence Center. Below, detailed information related to the payments is presented.

- Upfront payment: Initial payment performed unconditionally by the licensee at the moment of the license agreement. Usually a small proportion of the total deal.
- License fee: Amount of money the licensee pays to the licensor to give permission to use the patented technology. Usually a small proportion of the total deal.
- Milestone payments: Fees the licensee will only provide under certain conditions and landmarks stated previously in the license agreement. Usually, the harder a milestone is to accomplish, the higher the revenue. Considering other license

agreements provided by Global Data the estimated landmarks for the particular case of Nanotarg could be:

  - Milestone 1: Reaching Clinical trials phase I. If and only if the technology reached the first stage of clinical trials, the licensor will receive a certain amount of money.
  - Milestone 2: Reaching Clinical trials phase II. If and only if the technology reached the second stage of clinical trials, the licensor would receive a certain amount of money.
  - Milestone 3: Reaching Clinical trials phase I. If and only if the technology reached the third stage of clinical trials, the licensor would receive a certain amount of money.
  - Milestone 1: Reaching the commercial marketplace. If and only if the technology reached the market, the licensor would receive a certain amount of money.

- Royalty payment: A percentage of net profits obtained by the licensee if the technology reaches the market. It is known that the majority of licensing deals within the pharmaceutical industry include a percentage of 2.5-5% of royalties [117]. For this reason, a 5% of net sales is assumed in this particular case.

14.4.6. Profit and Loss

The profit and loss statement shows the estimated revenues and expenses of the company for a specific time period (2022-2031) [118]. This statement is done by considering all the incomes and costs stated in previous sections. With regards to utility costs, a value of 20.000 € per year has been estimated and only affects the period 2022-2024, since they derive from the activity of the group (pre-clinical phase) performed in that specific period.

The following *Tables 42 – 51* show the Profit and Loss statements over the period from 2022 to 2031.

Table 43: Profit and Loss statement in 2022

			TOTAL VALUE	January	February	March	April	May	June	July	August	September	October	November	December
PROFIT	Income	Upfront payment	82.800,00 €	6.900,00 €	6.900,00 €	6.900,00 €	6.900,00 €	6.900,00 €	6.900,00 €	6.900,00 €	6.900,00 €	6.900,00 €	6.900,00 €	6.900,00 €	6.900,00 €
		License fee	55.200,00 €	4.600,00 €	4.600,00 €	4.600,00 €	4.600,00 €	4.600,00 €	4.600,00 €	4.600,00 €	4.600,00 €	4.600,00 €	4.600,00 €	4.600,00 €	4.600,00 €
		Governmental grant	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 1	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 2	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 3	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 4	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Royalties	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
LOSS	HR	Partner 1 cost	3.000,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €
		Partner 2 cost	3.000,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €
		Employee cost	33.000,00 €	2.750,00 €	2.750,00 €	2.750,00 €	2.750,00 €	2.750,00 €	2.750,00 €	2.750,00 €	2.750,00 €	2.750,00 €	2.750,00 €	2.750,00 €	2.750,00 €
		Utilitiy costs	20.000,00 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €
	Depreciation	Equipment	500,00 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €
		Web page	333,30 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €
		Intellectual Property 1	3.000,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €
		Intellectual Property 2	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		R&D	50.000,00 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €
		Constitution expenses	500,00 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €
		Marketing activities	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		GROSS PROFIT	**24.666,70 €**	**3.722,23 €**	**3.722,23 €**	**3.722,23 €**	**3.722,23 €**	**3.722,23 €**	**3.722,23 €**	**3.722,23 €**	**3.722,23 €**	**3.722,23 €**	**3.722,23 €**	**3.722,23 €**	**3.722,23 €**

Table 44: Profit and Loss statement in 2023

			VALUE	January	February	March	April	May	June	July	August	September	October	November	December
PROFIT	Income	Upfront payment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		License fee	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Governmental grant	150.000,00 €	12.500,00 €	12.500,00 €	12.500,00 €	12.500,00 €	12.500,00 €	12.500,00 €	12.500,00 €	12.500,00 €	12.500,00 €	12.500,00 €	12.500,00 €	12.500,00 €
		Milestone 1	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 2	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 3	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 4	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Royalties	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
LOSS	HR	Partner 1 cost	3.090,00 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €
		Partner 2 cost	3.090,00 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €	257,50 €
		Employee cost	35.437,50 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €
		Utilitiy costs	20.000,00 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €
	Depreciation	Equipment	500,00 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €
		Web page	333,30 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €
		Intellectual Property 1	3.000,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €
		Intellectual Property 2	3.000,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €
		R&D	50.000,00 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €
		Constitution expenses	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Marketing activities	2.000,00 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €
		GROSS PROFIT	**29.549,20 €**	**2.462,43 €**	**2.462,43 €**	**2.462,43 €**	**2.462,43 €**	**2.462,43 €**	**2.462,43 €**	**2.462,43 €**	**2.462,43 €**	**2.462,43 €**	**2.462,43 €**	**2.462,43 €**	**2.462,43 €**

Table 45: Profit and Loss statement in 2024

			VALUE	January	February	March	April	May	June	July	August	September	October	November	December
PROFIT	Income	Upfront payment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		License fee	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Governmental grant		- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 1	220.800,00 €	18.400,00 €	18.400,00 €	18.400,00 €	18.400,00 €	18.400,00 €	18.400,00 €	18.400,00 €	18.400,00 €	18.400,00 €	18.400,00 €	18.400,00 €	18.400,00 €
		Milestone 2	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 3	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 4	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Royalties	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
LOSS	HR	Partner 1 cost	3.182,70 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €
		Partner 2 cost	3.182,70 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €	265,23 €
		Employee cost	35.437,50 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €
		Utilitiy costs	20.000,00 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €	1.666,67 €
	Depreciation	Equipment	500,00 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €	41,67 €
		Web page	333,30 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €	27,78 €
		Intellectual Property 1	3.000,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €
		Intellectual Property 2	3.000,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €
		R&D	50.000,00 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €
		Constitution expenses	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Marketing activities	2.000,00 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €
		GROSS PROFIT	**100.163,80 €**	**8.346,98 €**	**8.346,98 €**	**8.346,98 €**	**8.346,98 €**	**8.346,98 €**	**8.346,98 €**	**8.346,98 €**	**8.346,98 €**	**8.346,98 €**	**8.346,98 €**	**8.346,98 €**	**8.346,98 €**

Table 46: Profit and Loss statement in 2025

			VALUE	January	February	March	April	May	June	July	August	September	October	November	December
PROFIT	Income	Upfront payment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		License fee	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Governmental grant	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 1	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 2	414.000,00 €	34.500,00 €	34.500,00 €	34.500,00 €	34.500,00 €	34.500,00 €	34.500,00 €	34.500,00 €	34.500,00 €	34.500,00 €	34.500,00 €	34.500,00 €	34.500,00 €
		Milestone 3	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 4	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Royalties	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
LOSS	HR	Partner 1 cost	3.278,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €
		Partner 2 cost	3.278,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €	273,18 €
		Employee cost	35.437,50 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €	2.953,13 €
	Depreciation	Equipment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Web page	0,10 €	0,01 €	0,01 €	0,01 €	0,01 €	0,01 €	0,01 €	0,01 €	0,01 €	0,01 €	0,01 €	0,01 €	0,01 €
		Intellectual Property 1	3.000,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €
		Intellectual Property 2	3.000,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €
		R&D	50.000,00 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €	4.166,67 €
		Constitution expenses	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Marketing activities	2.000,00 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €
		GROSS PROFIT	**314.006,04 €**	**26.167,17 €**	**26.167,17 €**	**26.167,17 €**	**26.167,17 €**	**26.167,17 €**	**26.167,17 €**	**26.167,17 €**	**26.167,17 €**	**26.167,17 €**	**26.167,17 €**	**26.167,17 €**	**26.167,17 €**

Table 47: Profit and Loss statement in 2026

			VALUE	January	February	March	April	May	June	July	August	September	October	November	December
PROFIT	Income	Upfront payment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		License fee	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Governmental grant	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 1	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 2	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 3		- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 4		- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Royalties	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
LOSS	HH.RR	Partner 1 cost	3.376,53 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €
		Partner 2 cost	3.376,53 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €	281,38 €
		Employee cost	37.209,38 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €
	Depreciation	Equipment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Web page	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Intellectual Property 1	3.000,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €
		Intellectual Property 2	3.000,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €
		R&D	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Constitution expenses	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Marketing activities	2.000,00 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €
		GROSS PROFIT	- 51.962,43 €	- 4.330,20 €	- 4.330,20 €	- 4.330,20 €	- 4.330,20 €	- 4.330,20 €	- 4.330,20 €	- 4.330,20 €	- 4.330,20 €	- 4.330,20 €	- 4.330,20 €	- 4.330,20 €	- 4.330,20 €

Table 48: Profit and Loss statement in 2027

			VALUE	January	February	March	April	May	June	July	August	September	October	November	December
PROFIT	Income	Upfront payment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		License fee	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Governmental grant	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 1	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 2	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 3	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 4	745.200,00 €	62.100,00 €	62.100,00 €	62.100,00 €	62.100,00 €	62.100,00 €	62.100,00 €	62.100,00 €	62.100,00 €	62.100,00 €	62.100,00 €	62.100,00 €	62.100,00 €
		Royalties	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
LOSS	HH.RR	Partner 1 cost	3.477,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €
		Partner 2 cost	3.477,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €	289,82 €
		Employee cost	37.209,38 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €	3.100,78 €
	Depreciation	Equipment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Web page	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Intellectual Property 1	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Intellectual Property 2	3.000,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €	250,00 €
		R&D	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Constitution expenses	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Marketing activities	2.000,00 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €	166,67 €
		GROSS PROFIT	**696.034,98 €**	**58.002,92 €**	**58.002,92 €**	**58.002,92 €**	**58.002,92 €**	**58.002,92 €**	**58.002,92 €**	**58.002,92 €**	**58.002,92 €**	**58.002,92 €**	**58.002,92 €**	**58.002,92 €**	**58.002,92 €**

Table 49: Profit and Loss statement in 2028

			VALUE	January	February	March	April	May	June	July	August	September	October	November	December
PROFIT	Income	Upfront payment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		License fee	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Governmental grant	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 1	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 2	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 3	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 4		- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Royalties	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
LOSS	HH.RR	Partner 1 cost	3.582,16 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €
		Partner 2 cost	3.582,16 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €	298,51 €
		Employee cost	39.069,84 €	3.255,82 €	3.255,82 €	3.255,82 €	3.255,82 €	3.255,82 €	3.255,82 €	3.255,82 €	3.255,82 €	3.255,82 €	3.255,82 €	3.255,82 €	3.255,82 €
	Depreciation	Equipment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Web page	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Intellectual Property 1	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Intellectual Property 2	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		R&D	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Constitution expenses	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Marketing activities	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		GROSS PROFIT	- 46.234,16 €	- 3.852,85 €	- 3.852,85 €	- 3.852,85 €	- 3.852,85 €	- 3.852,85 €	- 3.852,85 €	- 3.852,85 €	- 3.852,85 €	- 3.852,85 €	- 3.852,85 €	- 3.852,85 €	- 3.852,85 €

Table 50: Profit and Loss statement in 2029

			VALUE	January	February	March	April	May	June	July	August	September	October	November	December
PROFIT	Income	Upfront payment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		License fee	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Governmental grant	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 1	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 2	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 3	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 4	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Royalties	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
LOSS	HH.RR	Partner 1 cost	3.689,62 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €
		Partner 2 cost	3.689,62 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €	307,47 €
		Employee cost	41.023,34 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €
	Depreciation	Equipment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Web page	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Intellectual Property 1	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Intellectual Property 2	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		R&D	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Constitution expenses	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Marketing activities	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		GROSS PROFIT	- 48.402,58 €	- 4.033,55 €	- 4.033,55 €	- 4.033,55 €	- 4.033,55 €	- 4.033,55 €	- 4.033,55 €	- 4.033,55 €	- 4.033,55 €	- 4.033,55 €	- 4.033,55 €	- 4.033,55 €	- 4.033,55 €

Table 51: Profit and Loss statement in 2030

			VALUE	January	February	March	April	May	June	July	August	September	October	November	December
PROFIT	Income	Upfront payment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		License fee	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Governmental grant	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 1	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 2	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 3	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 4	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Royalties		- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
LOSS	HH.RR	Partner 1 cost	3.800,31 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €
		Partner 2 cost	3.800,31 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €	316,69 €
		Employee cost	41.023,34 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €	3.418,61 €
	Depreciation	Equipment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Web page	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Intellectual Property 1	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Intellectual Property 2	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		R&D	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Constitution expenses	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Marketing activities	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		GROSS PROFIT	- 48.623,96 €	- 4.052,00 €	- 4.052,00 €	- 4.052,00 €	- 4.052,00 €	- 4.052,00 €	- 4.052,00 €	- 4.052,00 €	- 4.052,00 €	- 4.052,00 €	- 4.052,00 €	- 4.052,00 €	- 4.052,00 €

Table 52: Profit and Loss statement in 2031

			VALUE	January	February	March	April	May	June	July	August	September	October	November	December
PROFIT	Income	Upfront payment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		License fee	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Governmental grant	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 1	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 2	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 3	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Milestone 4	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Royalties	2.300.000,00 €	766.666,67 €	766.666,67 €	766.666,67 €	766.666,67 €	766.666,67 €	766.666,67 €	766.666,67 €	766.666,67 €	766.666,67 €	766.666,67 €	766.666,67 €	766.666,67 €
LOSS	HH.RR	Partner 1 cost	3.914,32 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €
		Partner 2 cost	3.914,32 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €	326,19 €
		Employee cost	43.074,50 €	3.589,54 €	3.589,54 €	3.589,54 €	3.589,54 €	3.589,54 €	3.589,54 €	3.589,54 €	3.589,54 €	3.589,54 €	3.589,54 €	3.589,54 €	3.589,54 €
	Depreciation	Equipment	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Web page	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Intellectual Property 1	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Intellectual Property 2	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		R&D	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Constitution expenses	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		Marketing activities	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €	- €
		GROSS PROFIT	**2.249.096,86 €**	**762.424,74 €**	**762.424,74 €**	**762.424,74 €**	**762.424,74 €**	**762.424,74 €**	**762.424,74 €**	**762.424,74 €**	**762.424,74 €**	**762.424,74 €**	**762.424,74 €**	**762.424,74 €**	**762.424,74 €**

14.4.7. Financial Indicators

Net Profit, Total Income and Cash Flow are three metrics which computed over a period reveal the evolution of a company.

With regards to the Total Income, it refers to the gross income or the earnings of the company before tax or cost deductions. It is computed by adding the revenues from all sources, in this case, the license agreement payments and the grant reward.

On the other hand, Net Profit refers to the real profit obtained by a company once taxes are subtracted from the Gross Profit, which is provided by the Profit and Loss statements and refers to the profit made by a company after subtracting the exploitation (HR and depreciation) and utility costs. With regards to the subtraction, it is associated to all corporations and depends on a determined tax, 25% in most of the cases [119]. In order to obtain the net profit, *Equation 4* is applied.

$$TAX = (Gross\ Profit) \cdot 0{,}25$$

Equation 4: TAX or subtraction calculation

Finally, the Cash Flow refers to the liquidity being transferred in and out of a company over a period. To obtain this indicator, the Net Profit of a present year is added to the bank cash of the previous one. As an example to compute the Cash Flow in 2023, *Equation 5* is applied.

$$Cash\ Flow(2023) = Net\ Profit(2023) + Cash(2022)$$

Equation 5: Cash Flow calculation

In *Table 53* and *Table 54*, the financial indicators over the period 2022 to 2031 are appreciable.

Table 53: Financial Indicators (2022-2026)

	2022	2023	2024	2025	2026
Net Profit	18.500,03 €	22.161,90 €	75.122,85 €	235.504,53 €	- 51.962,43 €
Total income/year	138.000,00 €	150.000,00 €	220.800,00 €	414.000,00 €	- €
Cash Flow	21.500,03 €	43.661,93 €	118.784,78 €	354.289,30 €	302.326,88 €

Table 54: Financial Indicators (2027-2031)

	2027	2028	2029	2030	2031
Net Profit	522.026,24 €	- 46.234,16 €	- 48.402,58 €	- 48.623,96 €	1.686.822,64 €
Total income/year	745.200,00 €	- €	- €	1.242.000,00 €	2.300.000,00 €
Cash Flow	824.353,11 €	778.118,95 €	729.716,37 €	681.092,42 €	2.367.915,06 €

14.4.8. Ratios

14.4.8.1. Profitability

Profitability ratios show whether a company is able to manage effectively the return on investment and the assets. Therefore, they work as indicators of good or bad financial health. [120].In this section, different profitability ratios are explained.

- Return on Common Equity: The ratio between the Net Profit of the company and the equity in terms of percentage. It is useful to measure the ability of a company to make profits from the investments. In other words, it reveals the profit each dollar of equity makes [121]. The equity for each year of the period 2022-2031 derives from the Balance Sheets available in Section 15.4.9 in this Appendix. A ROE around 15-20% is considered good [121]. In *Equation 6*, ROE formula is displayed.

$$ROE = \frac{Net\ Profit}{Equity} \cdot 100$$

Equation 6: ROE ratio formula

- Return On Investment (ROI): The indicator shows in terms of percentage to which extent a specific business produce gain from the use of capital (investments) [122]. It is measured with the partition of Income (e.g EBIT) by Investment (e.g the total assets). The higher this ratio is, the better [122].

$$ROI = \frac{Income}{Investment} = \frac{EBIT}{Total\ Assets} \cdot 100$$

Equation 7: ROI ratio formula

- EBITDA-to-sales ratio: Ratio between the EBITDA (Earnings Before Interests, Tax, Depreciation and Amortization) and the Total Income (or total revenues). In terms of percentage, it represents the remaining income after operating expenses. The formula used to acquire this ratio is appreciable in *Equation 8.*

$$EBITDA - to - sales = \frac{EBITDA}{Total\ Income} \cdot 100$$

Equation 8: EBITDA-to-sales ratio formula

- Gross Profit Margin: It reveals the relation of Gross Profit to Sales (Total Income) in terms of percentage. A high Gross Profit Margin reveals a good management [123].

$$Gross\ Profit\ Margin = \frac{Gross\ Profit}{Total\ Income}$$

Equation 9: EBITDA-to-sales ratio formula

14.4.8.2. Solvency

Solvency is also a very important feature for a business, hence, an insolvent business will be bankrupted [124]. A solvency indicator reveals the ability of a company to meet its debts and relates what is owned and what is owed to. *Equation 10* shows the formula for computing a solvency ratio.

$$Solvency\ ratio = \frac{Total\ Assets}{Total\ Liabilities}$$

Equation 10: Solvency ratio formula

14.4.8.3. Break-even Analysis

A break-even analysis is suitable for the assessment of economic feasibility of an emerging company [125]. Concretely, the break-even point is the point where no profit is made, and the revenues equal the expenses. It is expressed on euros € and represents the level of revenues required to cover costs and the volume of revenues from which profit is generated.

$$Break - even\ Point\ = Costs = Depreciation\ Costs + HH.RR\ costs$$

Equation 11: Break-even Point formula

14.4.9. Balance Sheets

Balance Sheets of period 2022-2031 appear in this section.

Table 55: Balance Sheet 2022

ASSETS		
Non-current assets		
Fixed assets		
	Equipment	1.500,00 €
Intangible assets		
	Web page	1.000,00 €
	Intellectual Propery 1	15.000,00 €
	R&D activities	200.000,00 €
	Constitution expenses	500,00 €
Current assets		
	Treasury	21.500,03 €
	VAT	525,00 €
TOTAL ASSETS		**240.025,03 €**
LIABILITIES		
	Equipment	1.000,00 €
	Web page	666,70 €
	Intellectual Propery 1	12.000,00 €
	VAT	525,00 €
	R&D activities	150.000,00 €
	Constitution expenses	- €
TOTAL LIABILITIES		164.191,70 €
	EQUITY	75.833,32 €

Table 56: Balance Sheet 2023

ASSETS		
Non-current assets		
Fixed assets		
	Equipment	1.500,00 €
Intangible assets		
	Web page	1.000,00 €
	Intellectual Propery 1	15.000,00 €
	R&D activities	200.000,00 €
	Constitution expenses	500,00 €
	Intellectual Propery 2	15.000,00 €
	Marketing activities	10.000,00 €
Current assets		
	Treasury	43.661,93 €
	VAT	- €
TOTAL ASSETS		**271.661,93 €**
LIABILITIES		
	Equipment	500,00 €
	Web page	333,40 €
	Intellectual Propery 1	9.000,00 €
	Intellectual Property 2	12.000,00 €
	VAT	- €
	R&D activities	100.000,00 €
	Constitution expenses	- €
	Marketing activities	8.000,00 €
TOTAL LIABILITIES		129.833,40 €
	EQUITY	141.828,52 €

Table 57: Balance Sheet 2024

ASSETS		
Non-current assets		
Fixed assets		
	Equipment	1.500,00 €
Intangible assets		
	Web page	1.000,00 €
	Intellectual Propery 1	15.000,00 €
	R&D activities	200.000,00 €
	Constitution expenses	500,00 €
	Intellectual Propery 2	15.000,00 €
	Marketing activities	10.000,00 €
Current assets		
	Treasury	118.784,78 €
	VAT	- €
TOTAL ASSETS		**346.784,78 €**
LIABILITIES		
	Equipment	0,00 €
	Web page	0,10 €
	Intellectual Propery 1	6.000,00 €
	Intellectual Property 2	9.000,00 €
	VAT	- €
	R&D activities	50.000,00 €
	Constitution expenses	- €
	Marketing activities	6.000,00 €
TOTAL LIABILITIES		71.000,10 €
	EQUITY	275.784,67 €

Table 58: Balance Sheet 2025

ASSETS		
Non-current assets		
Fixed assets		
	Equipment	1.500,00 €
Intangible assets		
	Web page	1.000,00 €
	Intellectual Propery 1	15.000,00 €
	R&D activities	200.000,00 €
	Constitution expenses	500,00 €
	Intellectual Propery 2	15.000,00 €
	Marketing activities	10.000,00 €
Current assets		
	Treasury	354.289,30 €
	VAT	- €
TOTAL ASSETS		**582.289,30 €**
LIABILITIES		
	Equipment	- €
	Web page	0,00 €
	Intellectual Propery 1	3.000,00 €
	Intellectual Property 2	6.000,00 €
	VAT	- €
	R&D activities	- €
	Constitution expenses	- €
	Marketing activities	4.000,00 €
TOTAL LIABILITIES		13.000,00 €
	EQUITY	569.289,30 €

Table 59: Balance Sheet 2026

ASSETS		
Non-current assets		
Fixed assets		
	Equipment	1.500,00 €
Intangible assets		
	Web page	1.000,00 €
	Intellectual Propery 1	15.000,00 €
	R&D activities	200.000,00 €
	Constitution expenses	500,00 €
	Intellectual Propery 2	15.000,00 €
	Marketing activities	10.000,00 €
Current assets		
	Treasury	302.326,88 €
	VAT	- €
TOTAL ASSETS		**530.326,88 €**
LIABILITIES		
	Equipment	- €
	Web page	- €
	Intellectual Propery 1	- €
	Intellectual Property 2	3.000,00 €
	VAT	- €
	R&D activities	- €
	Constitution expenses	- €
	Marketing activities	2.000,00 €
TOTAL LIABILITIES		5.000,00 €
	EQUITY	525.326,88 €

Table 60: Balance Sheet 2027

ASSETS		
Non-current assets		
Fixed assets		
	Equipment	1.500,00 €
Intangible assets		
	Web page	1.000,00 €
	Intellectual Propery 1	15.000,00 €
	R&D activities	200.000,00 €
	Constitution expenses	500,00 €
	Intellectual Propery 2	15.000,00 €
	Marketing activities	10.000,00 €
Current assets		
	Treasury	824.353,11 €
	VAT	- €
TOTAL ASSETS		**1.052.353,11 €**
LIABILITIES		
	Equipment	- €
	Web page	- €
	Intellectual Propery 1	- €
	Intellectual Property 2	- €
	VAT	- €
	R&D activities	- €
	Constitution expenses	- €
	Marketing activities	- €
TOTAL LIABILITIES		- €
	EQUITY	1.052.353,11 €

Table 61: Balance Sheet 2028

ASSETS		
Non-current assets		
Fixed assets		
	Equipment	1.500,00 €
Intangible assets		
	Web page	1.000,00 €
	Intellectual Propery 1	15.000,00 €
	R&D activities	200.000,00 €
	Constitution expenses	500,00 €
	Intellectual Propery 2	15.000,00 €
	Marketing activities	10.000,00 €
Current assets		
	Treasury	778.118,95 €
	VAT	- €
TOTAL ASSETS		**1.006.118,95 €**
LIABILITIES		
	Equipment	- €
	Web page	- €
	Intellectual Propery 1	- €
	Intellectual Property 2	- €
	VAT	- €
	R&D activities	- €
	Constitution expenses	- €
	Marketing activities	- €
TOTAL LIABILITIES		- €
	EQUITY	1.006.118,95 €

Table 62: Balance Sheet 2029

ASSETS		
Non-current assets		
Fixed assets		
	Equipment	1.500,00 €
Intangible assets		
	Web page	1.000,00 €
	Intellectual Propery 1	15.000,00 €
	R&D activities	200.000,00 €
	Constitution expenses	500,00 €
	Intellectual Propery 2	15.000,00 €
	Marketing activities	10.000,00 €
Current assets		
	Treasury	729.716,37 €
	VAT	- €
TOTAL ASSETS		**957.716,37 €**
LIABILITIES		
	Equipment	- €
	Web page	- €
	Intellectual Propery 1	- €
	Intellectual Property 2	- €
	VAT	- €
	R&D activities	- €
	Constitution expenses	- €
	Marketing activities	- €
TOTAL LIABILITIES		- €
	EQUITY	957.716,37 €

Table 63: Balance Sheet 2030

ASSETS		
Non-current assets		
Fixed assets		
	Equipment	1.500,00 €
Intangible assets		
	Web page	1.000,00 €
	Intellectual Propery 1	15.000,00 €
	R&D activities	200.000,00 €
	Constitution expenses	500,00 €
	Intellectual Propery 2	15.000,00 €
	Marketing activities	10.000,00 €
Current assets		
	Treasury	1.624.748,41 €
	VAT	- €
TOTAL ASSETS		**1.852.748,41 €**
LIABILITIES		
	Equipment	- €
	Web page	- €
	Intellectual Propery 1	- €
	Intellectual Property 2	- €
	VAT	- €
	R&D activities	- €
	Constitution expenses	- €
	Marketing activities	- €
TOTAL LIABILITIES		- €
	EQUITY	1.852.748,41 €

Table 64: Balance Sheet 2031

ASSETS		
Non-current assets		
Fixed assets		
	Equipment	1.500,00 €
Intangible assets		
	Web page	1.000,00 €
	Intellectual Propery 1	15.000,00 €
	R&D activities	200.000,00 €
	Constitution expenses	500,00 €
	Intellectual Propery 2	15.000,00 €
	Marketing activities	10.000,00 €
Current assets		
	Treasury	3.311.571,05 €
	VAT	- €
TOTAL ASSETS		**3.539.571,05 €**
LIABILITIES		
	Equipment	- €
	Web page	- €
	Intellectual Propery 1	- €
	Intellectual Property 2	- €
	VAT	- €
	R&D activities	- €
	Constitution expenses	- €
	Marketing activities	- €
TOTAL LIABILITIES		- €
	EQUITY	3.539.571,05 €