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Keys to success in creating a Biotechnological Start-Up:
A practical example

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KEYS TO SUCCESS IN CREATING A BIOTECHNOLOGICAL START-UP: A PRACTICAL EXAMPLE

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ABSTRACT

The business environment in the Bioeconomy area has changed over the past few years. In addition to the great companies and the multinational ones, there is an increase of small biotechnological companies with revolutionary ideas that diversifies and makes the sector more versatile: The Start-ups.

Not only a good idea is important, there are also other crucial aspects that must be considered, such as the type of society, the financing of the product and/or the company, the protection of the patents, etc.

All these elements are sometimes ignored by us or wrongly focused due to an ignorance in the area of Business Management and Economy. Is for this reason that this Final Project has been developed in order to be used as a guide for the creation of a Biotechnological Start-up , analysing the steps that must be followed from the beginning (the foundation) and which are the keys for the success of it, also studying the strengths and disadvantages that are specific to a biotech company.

All this material is illustrated with a hypothetical practical example of the creation of a biotechnological Start-up .

KEYWORDS

Start –up, biotechnology, management, success, investors, patents and idiosyncrasies.

CLAVES DEL ÉXITO PARA LA CREACIÓN DE UNA START-UP BIOTECNOLÓGICA: UN EJEMPLO PRÁCTICO

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RESUMEN

El ambiente empresarial en el área de la Bioeconomía ha cambiado en los últimos años. Además de las grandes empresas y las firmas multinacionales, surgen cada vez más empresas pequeñas de carácter biotecnológico de nueva creación con ideas revolucionarias que hacen que se diversifique el sector y lo hacen más versátil: Las Start-up.

Además de una buena idea, son cruciales otros aspectos a tener en cuenta como el tipo de sociedad, la financiación del producto y/o empresa, la creación de las patentes, etc.

Todos estos son elementos que a veces se nos pasan por alto o no los enfocamos de manera correcta principalmente por el desconocimiento en el área de administración de empresas y economía. Es por ello que este Trabajo Final de Grado sirve como guía para la creación de una Start-up biotecnología, analizando los pasos a seguir desde el principio (Fundación de la empresa) y cuáles son las claves para el éxito de la misma, estudiando también los inconvenientes propios del sector biotecnológico.

Todo esto ilustrado con un ejemplo práctico de una Start-up biotecnológica hipotética.

PALABRAS CLAVE

Start –Up, biotecnología, gestión, inversores, patentes e idiosincrasias.

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1. INTRODUCTION

1.1 START-UP'S CONCEPT

Nowadays biotechnology is increasing its presence in the national and global Economy, due to the importance of innovation and development in the business world, which explains the birth of Start-ups.

Although the definition of a Start-up is ambiguous, owing to the fact that usually are the company's own founders who make use of this term, it can be appointed as specific-category companies that have been recently created (Annex 1) which operate in high-tech sectors and show a trend towards innovation (March, 2011) .

Sometimes, Start-ups are not considered as a company as such, but they are understood as an idea that aspires to be a business, due to the fact that they usually do not have a detailed business plan and a clear organization and management. It would be possible to relate this to the scientific method, considering that one startup is just an experiment from which the final project (A business) can be generated. Once the hypotheses, that would be equivalent to the objectives (satisfaction of the clients, commercialization of a product, etc.), are established, a strategy is settled down in order to fulfil this objectives, creating a product and observing if the strategy is bringing positive results, that is to say, if the objectives defined previously haven been achieved (initial hypotheses).

Once the exponential growth of the business has been reached, the Start-up undergoes through a series of structural changes, for instance a better organizational structure or the adopting of new strategies. Depending on the Start-up, this growth can be produced in different years, but the usual duration of this process is 2 years, in which the Start-up starts to be a “complete” business and leaves aside its condition of a new-creation company. There are diverse events that can indicate this , as for example the fact that the company is profitable , which is very difficult to be accomplished in two years in the case of biotech Start-ups ; that the company has trade on the stock market, or that it has fused another Start-up or it has been acquired by a greater company. These would be characteristics which are easily detected , but there are also other details that can indicate that one Start-up is becoming a mature company , for instance the regularization and stability of the working days and of the hours dedicated to the company (in the case of a Start-up, entrepreneurs spend most of their day in their new creation.

1.2 SITUATION AND INCREASE OF BIOTECH COMPANIES IN SPAIN

Biotechnology is an upward trend sector for what refers to entrepreneurship. Many scientists have seen in this type of businesses an opportunity to be able to develop their idea and to get profit from it. Usually it is thought that these Start-ups consists only of companies based on lines of research, whereas it is not known that also there are biotech Start-ups whose main work is not to research, but to offer services to other companies and/or institutions, as for example the loan of materials, genetic consultancy, analyses, etc.

Biotechnology in Spain, as it is reflected in the last annual report of ASEBIO (The Spanish Association of Biocompanies) of 2016, generated over the national Economy, in a direct, indirect and induced way, in 2015, an impact of 8,6% on the GDP (Gross Domestic Product), with a total number of 930.000 employees. Analysing the businesses which are dedicated specifically to biotechnology, they contributed with more than € 8.2 million and with 130000 employees, which equate to a 0.8% of the GDP.

On the other hand, analysing the companies whose main activity is biotechnology, the ones which use it as a secondary business, and the ones which utilise it as a tool, they employed directly more than 182000 people in 2015. In addition, it has to be highlighted that there was a change of tendency in 2015, as there was an increase of the number of companies involved in biotechnology, 240 more than in 2014 (Figure 1). As we can see in the graph, although there was an economic downturn in Spain, the number of companies engaged in biotechnology increased between 2009 and 2012, due to the innovation of the sector (Annex 1).

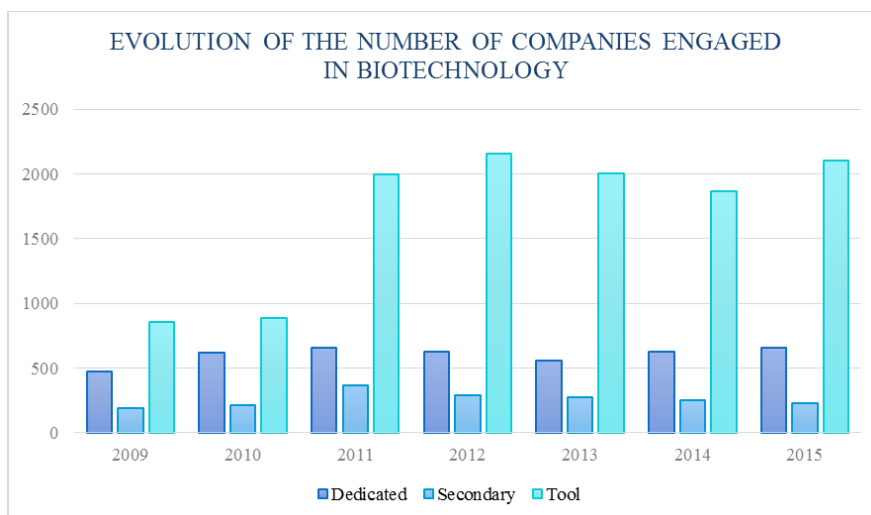


Figure 1: Graph which represents how the number of biotechnological companies has evolved during the last years. (ASEBIO, 2017)

Regarding the protection of the intellectual property of Spanish biotechnological companies, in 2016 there were published 813 patents, including the granted ones and the applications, which represents a small decrease of 11% with respect to 2015. Although the European Patent Office (EPO) is the one which receives more applications, the Spanish Trademark and Patent Office (SPTO) is the one with a higher number of granted patents (Table 1).

Table 1 :Number of patent applications and patents granted to Spanish biotechnology entities (2016) . The public databases of patents are: Spanish Trademark and Patent Office (SPTO), the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO), Japan Patent Office (JPO) and the World Intellectual Property Organization (WIPO-PCT). (ASEBIO,2017)

	OEPM	EPO	USPTO	JPTO	PCT	TOTAL
Applications	103	190	53	21	135	502
Granted	143	117	31	20	(N/A)	311
TOTAL	318	307	84	41	62	813

1.3 MANAGEMENT VS SCIENCE

A student who is coursing an university degree related to life sciences , can , when he/she finishes the degree or during his/her professional career , have an idea of a company related to the biotech sector. Nevertheless, what usually happens is that graduates continue with their postgraduate studies and work in research or in a private company , producing biotechnological goods, doing quality controls , working as consultants ,etc .

In addition to the difficulty of having an original and successful business idea, there is also another handicap in the biotech sector : the general absence of entrepreneurial spirit. It can be due to a lack of interest in Business and Economy, as well as the fear to risk and to start the adventure that entails the creation of a biotechnological Start-up.

It is not only important an interest towards the management of biotech businesses, but also it is essential the academic education in these areas. For that reason, it has been done a *Survey on the interest and the academic background in Entrepreneurship of life sciences' students* (Annex 2) , asking 63 students of Biotechnology (UPV), Biology (UV) and Biochemistry and Biomedical Sciences (UV).

Of some of the questions included in the survey, there are a few of them which need to be highlighted. For instance, in Question 5, “*On a scale from 1 to 5 in which 5 implies “much” and 1 “very little”, how important do you think it is to have this type of modules in the Curriculum of*

your degree, most of the students answered between a qualification of 3 and 5, which indicates that they think that these kind of modules are important in this type of degrees (Figure 2) .

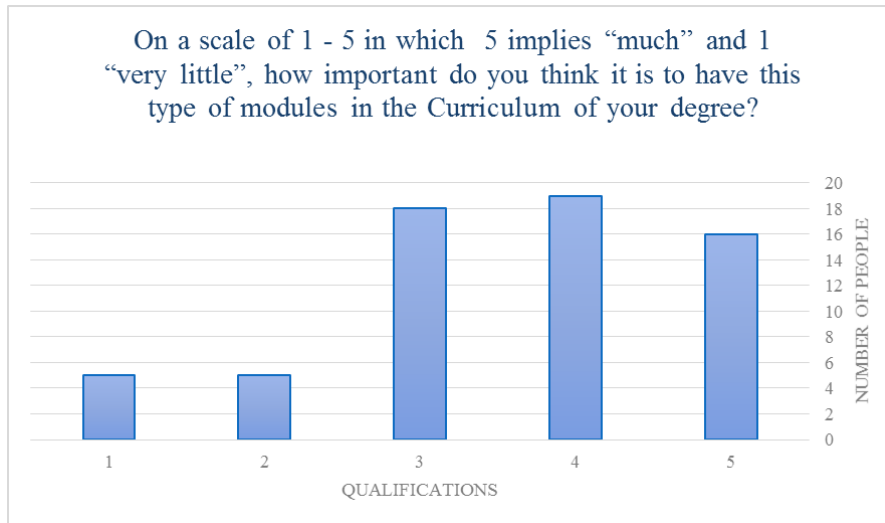


Figure 2 Graph which represents how important are business modules for Life Sciences’ students (Annex 2)

Although most of the consulted students think that it is important to study business in this type of degrees, when they need to apply everything they have learned in these modules, they are sceptical about the frequency with which they are going to use the knowledge acquired and about their own capacity to create a biotech Start-up, which is demonstrated in the answers to Question 6, “ On a scale of 1-5 in which 5 implies “much “and 1 “never”, with which frequency do you think you are going to apply these knowledge of economy in your professional future?” (Figure 3) and to the ones to Question 9 “Do you think that with the knowledge that you have in the area of business and management you would be able to create a Biotech business in the case you had an idea to develop?” (Figure 4) .

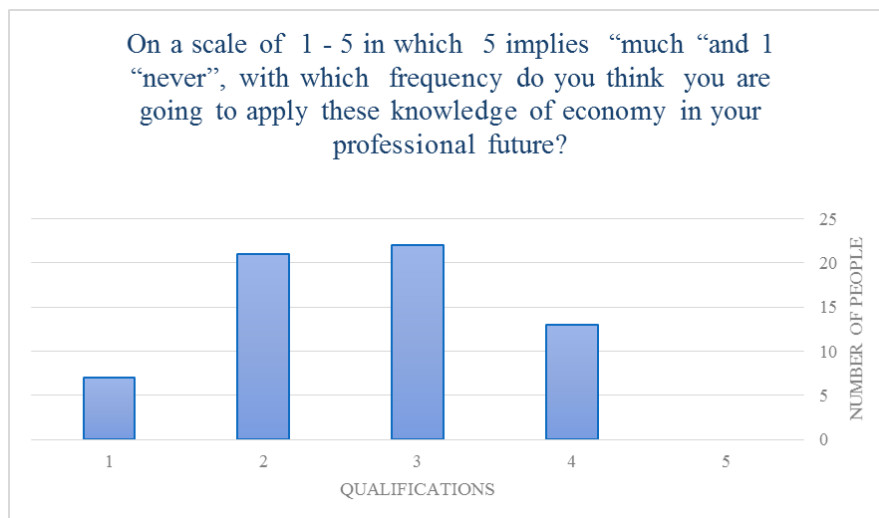


Figure 3 : Graph which represents the frequency with which the students of Life Sciences think they are going to use the topics that they have studied in the modules of Business (Annex 2)

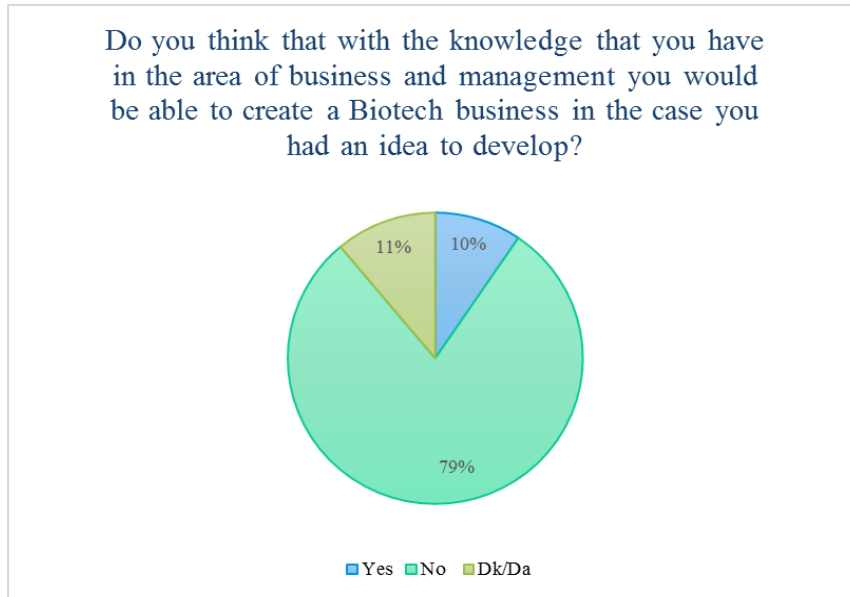


Figure 4: Graph which represents the percentage of survey respondents who think that they are able to create a Biotech company with the knowledge they have in Business. (Annex 2)

Furthermore, it is also important to know which is the entrepreneurial spirit of the students of these degrees, shown by the answers to question 8, “*Have you thought about creating a biotechnological Start-up?*”, in which only 30% of the ones polled answered that they had thought about starting a biotech Start-up (Figure 5).

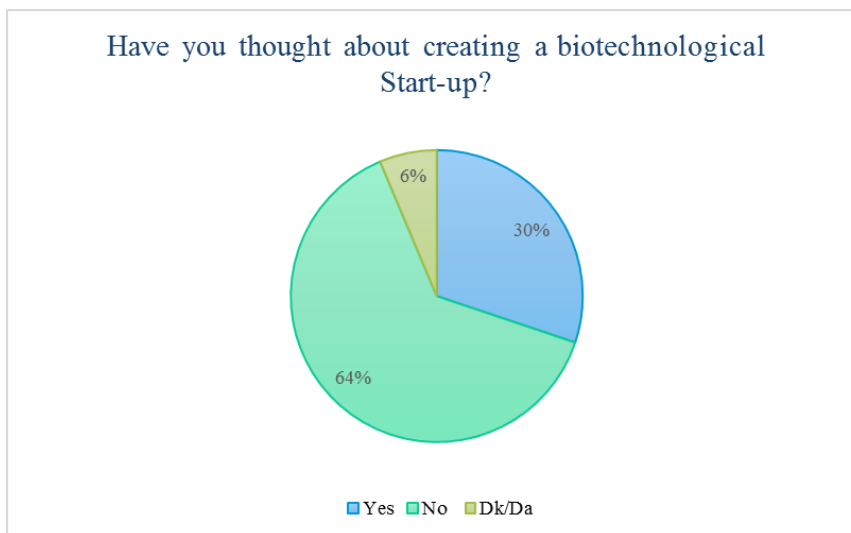


Figure 5: Graph which represents the percentage of student who have thought about creating a biotech business. (Annex 2)

These findings show that this Final Project could help students of areas related to biotechnology and graduates, who might not remember what they have learned in their Economy classes or have not studied any module of management at University, making them easier to know how they must create a biotechnological Start-up, in order to have success with it.

1.4 PRACTICAL EXAMPLE: OLMIBEX

The idea is to use this example to facilitate the understanding of the different key steps of the foundation of a successful Biotech Start-up, being used in some of them to clarify the concepts. This is a hypothetical Start-up, so any resemblance to real companies, people or accounts is strictly a coincidence

Nowadays, the lack of nutrients at a global level is an undeniable fact. During the first decade of this century, the number of people who suffered hunger had been reduced, although in the last years it has increased again due to the military conflicts, as well as the successive natural disasters that devastated zones with low resources and/or those whose main food supply was traditional agriculture. (IFPRI, 2016)

In 2017 the annual United Nations report on world food security and nutrition assured that in 2016 there were 815 million people in state of hunger, 38 million more than the previous year (*FAO et al, 2017*).

That is the reason for the creation of OLMIBEX (Figure 6), a SL (*Sociedad de Responsabilidad Limitada*) constituted by four promotional partners, who are specialized in different sectors of Biotechnology, working together with the same objective: To develop innovating strategies which involve biotechnology to end with hunger in developing countries, as well as to make use of the knowledge in the previously mentioned area to advise the companies of the sector on scientific and management issues .



Figure 6: OLMIBEX's Logo

The main activity of the Start-up would be to act as consultants to the biotech companies of the agro-alimentary industry, using the money earned, apart from the one of the funders; and the contacts generated, to develop agro- alimentary optimised products to help developing countries. The idea to achieve this is to be in contact with the Government of the countries whose inhabitants suffer from absence of food in addition to Non- Governmental Organizations and/or other Societies that could be involved in these areas. Furthermore, the inhabitants of the countries in

which the company will work, will be involved in the project in a direct or indirect way, in order to contribute all together with our small but effective help to achieve a healthier society.

Due to the great ambition that implies this project, we will have help from national universities and entrepreneurs of the sector, which may support and collaborate with this plan, with the purpose of obtaining an expansion along the Spanish territory, as well as at European and Global level.

2. OBJECTIVES

The main objective of this project is to establish the fundamental steps in the formation of a biotechnological Start-up, not only explaining which they are, but also providing advice on what is the best way to carry them out, detailing and specifying the crucial aspects to have success in the foundation of a biotech company.

On the other hand, it will also be explained which are the idiosyncrasies of the sector, thus specifying the difficulties that are presented to a biotechnological entrepreneur.

In addition to all this, it is also a purpose of this project to analyze and contextualize the current situation of the biotech Start-ups in Spain, as well as to know the opinion of the students of Life Sciences' degrees about entrepreneurship.

3. MATERIALS AND METHODS

This bibliographic project has been developed searching for information about the creation of biotechnological Start-ups, as well as about elements that are intrinsic to the sector and that may affect biotech companies. In order to compile all the necessary data it has been essential the use of articles about economic management of biotechnological companies, written by scientists of the sector, as well as the web pages of companies and entities dedicated to business teaching and biotech consultants. Information from institutions such as the European Patent Office (EPO) or regulations included in the “Boletín Oficial del Estado” (BOE) have also been used.

On the other hand, it has been a great help for this thesis the collaboration of Manuel Perez Alonso, founder of IMEGEN and professor at the Genomics' department of the University of Valencia, for the realization of the interview included in annex 1, as well as the participation of the students of the degree in biotechnology (UPV). Biology, and Biochemistry and Biomedical Sciences (UV), who carried out the survey about entrepreneurship, included in annex 2 and created with Google Forms. Furthermore, during the degree there have been some modules whose academic contents have made easier the process of developing this project, for instance “Biotechnology Business Economics” and “Legal and Sociological Aspects of Biotechnology”, although all the modules of the degree are needed in order to apply the previous ones on dairy life.

4. KEY STEPS FOR THE FOUNDATION OF OUR BIOTECH START-UP

Each individual biotech Start-up is unique, and for that reason, the steps that must be followed in each one are different, being some steps common for all of them, as the business plan, the funding events or the company formation. In Figure 7, it is shown a diagram which consist of the life of a science Start-up , starting with its foundations and finishing with its acquisition by a bigger company, or offering its stock to the public , in other words, it starts with the initial public offering (IPO) (Tajonar, 2014).

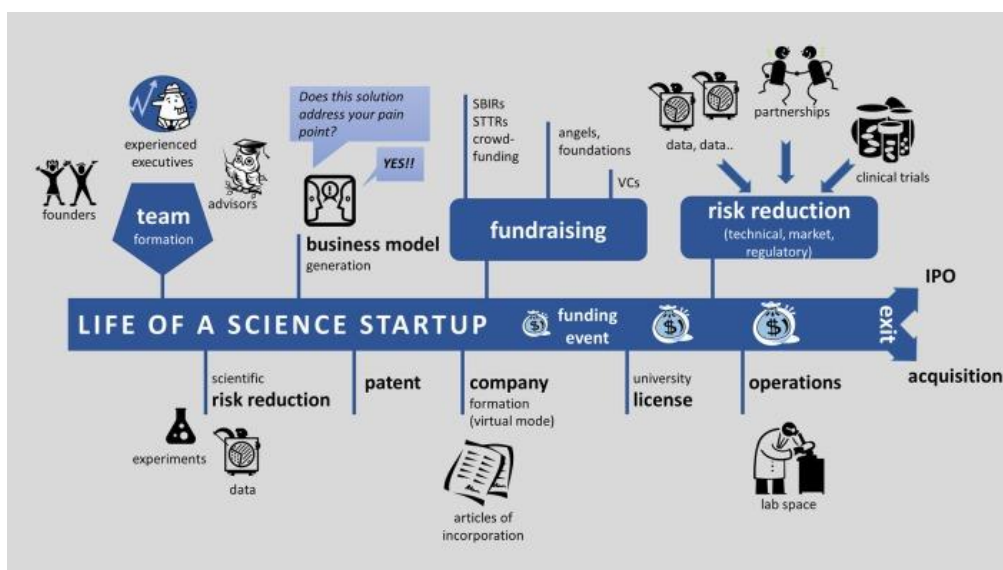


Figure 7: Diagram which represents the life of a science Start-up (Tajonar, 2014)

The following steps and definitions will help the reader to understand better the process of starting a biotechnological Start-up, explaining concepts which are crucial to achieve success and to obtain a profit from the business idea.

4.1 BUSINESS PLAN

The business plan is an essential document for all the companies, in order to establish their way of working as well as to seek for money to finance its projects, showing that our Start-up is viable and that the concepts to be successful are clearly (Block, 2009). Each business is different, and so is its business plan, as it can be approached in different ways, always being realistic but having into account that we need to convince the person who is reading it (Cohen, 2002) .

This is an example of how a Business Plan of a Biotech Start-up can be structured (Cohen, 2002; Hoyt, 2011):

a) Executive Summary

It is a brief description of the company that must get the reader's attention and explain the business as concisely as possible, as many investors will read this and take the decision of continuing reading or just stop and start with another proposal (Block, 2009). In the case of OLMIBEX, in addition to what was mentioned before in the description of the example, it also must be included the key points of the strategic plan, the revenue model, and a summary of the financial plan (Ward, 2017).

b) Management

Introduce your management team. Give some background on them and highlight their strengths as it pertains to the venture and their position within it. A poor management team can easily drive away investors, so be sure that your team looks good both on paper and in person (Haden, 2015). You should have enough talent on your team to realize your objectives. If there are any key skill gaps that will be addressed through outsourcing, be sure to address those in your operating plan. This is not just essential for the business plan, but also to be sure that we are going to success with our start.-up it is vital to have a good team of people who dedicate full-time to the project to achieve a common objective (Hofstrand, 2009).

There are two questions that must be answered in this section:

1. Who are the main leaders of the project? Which are their skills, professional backgrounds, experiences and education?
2. Which responsibilities do each of the leaders have? Who is considered as an authority? (Haden, 2015)

The description of the main leaders in OLMIBEX would be:

1. Javier Olmos Becerra, Founder and CEO (Chief Executive Officer)

Javier has over two years of experience in the Bioconsulting business, advising the main Biotech and Pharma multinationals in order to help them to optimise their production and suggesting them the analysis of new potential markets. In addition to this, Javier has been a volunteer in Swaziland, helping to collect and to develop new techniques to make the farmers' life easier, where he met the rest of the founders. This experience was what motivated the group to look for a solution for finishing with hunger around the world. He studied the degree in Biotechnology at the Polytechnic University of Valencia (UPV) and then, he did a MSc.

In Medical Biotechnology at the Royal Institute of Technology in Stockholm (KTH). Javier is practical, reliable and efficient.

2. María Ibáñez García, Founder and Marketing Manager

Maria has been working in the nutrition sector for five years, being in the marketing area during the last three years, developing new healthy products which can attract the consumers. In addition, she helped in Swaziland to establish new diets in the school of the main cities. She studied the degree in Nutrition and Dietetics at King's College London and then a Master in Nutrition And Health Promotion at Simmons College (Boston). Apart from this, Maria is very useful at the company because she is outgoing, enthusiastic and communicative.

3. Christian Gómez Navarro, Chief Financial Officer (CFO) or Controller

Christian is the main responsible for the economics part of the business, as he has worked for 7 years as the director of the accounting department of Nestle, having a high experience in the finances of the nutrition sector, not only in the industrial side, but also at a lower level, as for example the accounting of the local farmers in Swaziland when he was a volunteer there. He studied Economics at the University of Valencia (UV) and then a MSc in Accounting and Finance at the London School of Economics and Political Science (LSE). Christian is strategic and discerning.

4. Sofia Fernández Ruiz , Production Manager

Sofia has specific industry knowledge and experience in the sector of biotechnology applied to food industry. She has worked in the R&D department of different multinationals for six years, developing new technologies for improving the yields of productions and new varieties of crops. She studied a degree in Biotechnology at the Polytechnic University of Valencia (UPV), a master in Advanced Biotechnology at the University of Barcelona (UB) and a PhD at the Institute for Plant Molecular and Cell Biology (IBMCP). She is single-minded, self-starting and dedicated.

c) Marketing Plan

It has to give information about the parameters of the sector and about the companies that are similar to yours. In this part it is important to analyse the size of the sector (demographics and segmentation) , its opportunities and difficulties, who are the clients, the market tendency, the perspectives of future, etc (Pestle analysis, 2015). All of this has to be supported by data and statistics. In the example of OLMIBEX, we would need to search for information in the national

and international registers to obtain statistics of the sector, in addition to look for data about biotech consultancy and food innovation, not just focusing on big multinationals (Nestle, , Danone, Unilever, Mondelez,etc) (Robert, 2016) , but also national and regional Small and Medium-sized Enterprises (SMEs) .

You need to show how you are going to sell your product/service and which marketing channels are you going to use to do it, being Internet and the commercial and cooperative relations with public and private institutions, the best way to show our company to future clients. Moreover it must be included which strategies are going to be followed in order to hit the target consumer and which is going to be the relationship between your company and the market (NetMBA, 2010).

In order to study the viability of the Start-up in the market it is usually used a SWOT analysis, in which the Strengths, Weaknesses, Opportunities and Threats of the business are included in an organised way (Gregory, 2018).

With this diagram it is easier to connect all the elements in a visual way to facilitate its understanding, making easier to evaluate if a business is viable or not, and if the answer is yes, it is a good starting point to design which strategies must be followed to correct the weaknesses, face the threats, maintain the strengths and take advantage of the opportunities (Kokemuller, 2018).

This matrix makes a distinction between internal and external factors. In the internal ones, it is necessary to analyse the competitors and compare their situation with the one of our company, obtaining information about the aspects in which the Start-up presents strengths or weaknesses in comparison with the competition.

On the other hand, the external factors show the opportunities and the weakness that the business can have in the future, as for example changes in the market's tendency, law, etc (Dyson, 2002).

In the example of the SWOT analysis of OLMIBEX (Table 1) some elements which can be present in other Start-ups have been included, so it can be useful for other biotech Start-ups to do their own matrix.

Table 2 . SWOT analysis' matrix of OLMIBEX

	Internal analysis	External analysis
Positive	STRENGTHS	OPPORTUNITIES
	Highly qualified staff Advanced technical knowledge Loyalty of the workers High standards of service	Change in trends and development of the society Technological progress Continuous growth sector
Negative	WEAKNESSES	THREATS
	No experience as entrepreneurs Small infrastructures Business' diversification	Negative law changes New competitors

d) Competition

It can be included in the Market analysis. Be informed about the possible competitors before starting to look for investors is important. Denying their existence is just going to make the business plan unrealistic and utopian (Cohen, 2002).

The main objective of this section is to prove that the rest of companies only cover part of the necessities of the clients while ours fill them fully or at least, more than the others; being our service faster, cheaper, more environmentally friendly, etc. (BRI, 2014)

However, this superiority over our competitors will be ephemeral , so we will need to include a forecast of how much time do we think that our business will be a better option than the rest, having to innovate or to bring a new product to the market ("adapt or perish", as they say).(Cohen, 2002)

e) Scientific Background

Although science is the main key for success in our Biotech Start-up, it is important to take into account who is going to read this business plan, so it cannot be written as a scientific article or a review. (Cohen, 2002) In this part of our document we need to clarify what our product is about, its functions, and the scientific evidence around it and last but not least, the possible economic benefits that could result from its sale and the time needed to develop the product.(Hoyt, 2011) Obviously it has to be explained using scientific terms but in a simple way as it is possible that the reader has a low technical knowledge in biotechnology (Cohen, 2002).

f) Strategy for growth

It is a plan that shows how your Start-up can get from where it is today to where you want it to be. . Although you can keep this part to yourself, it is better to show to the possible investors which are your plans for the future, giving them confidence about the idea of financing your project (INFO ENTREPRENEURS, 2009).

To grow in this sector you will need to undertake some efforts to pursuit your objectives, for instance the sale of your product in less regulated international markets in order to reduce costs, establishing joint ventures with strategic partners who can help you in your success process.

But not only must this be included in this section, also simple things as how you will expand into new markets or where are you going to look for new customers. Including a flow chart with all the things you plan to do to achieve your goals will make easier to the investors to know how much money you need for everything (Cohen, 2002).

g) Operating Plan

Here you need to explain how your new biotech Start-up is going to operate, explaining where your business is based, which is your organizational plan, who your suppliers are and the premises and equipment needed (Dahl, 2011).

h) Financial plan

It consists mainly on presenting your project in a monetary context. It is recommended to include a 3-5 years “Statements of Operations and Cash flows”. In case your Start-up has already done the research and the development stage it is important to include the balance sheet.

All the figures and every aspect of the financial plan has to be clear for the investor who is going to read it. Moreover, don't overestimate your revenues because otherwise the investors will lose their confidence on you. . It's better to have a slightly worse financial outlook that's defensible (Cohen, 2002).

In addition to all mentioned before, here there are some useful tips about the things that you must/mustn't do when you write a business plan (Cohen, 2002):

Table 3 . Do's and Don'ts in a Business Plan (Cohen,2002)

DO	DON'T
<ul style="list-style-type: none"> • Highlight the business opportunities associated with the venture's science • Be realistic in establishing milestones • Create the plan around "moderate" assumptions • Plan an infrastructure that will accommodate growth • Write clearly and use graphics when appropriate 	<ul style="list-style-type: none"> • Mistake an exciting technology for a business • Ignore the weaknesses in your company or plan • Overlook the competition • Include untruths, semi-truths, or wishful thinking • Write anything you cannot defend in meetings with investors

Business Model Canvas

It consists of a brief outline of the future Business Plan , being used in the Start-ups to know easily and at a glance how is the company itself and what are its key areas, being very useful to establish which strategies must be followed, the relationship between the elements included in it or the consequences that may have a modification of any of them (Greenwald, 2012).

The Business model canvas is composed by 9 building blocks (Das, 2017) :

- a) **Key partners:** Includes the companies, entities and people that will be part of the company's allies.
- b) **Customer segment:** It describes who the main clients are in a general way.
- c) **Value propositions:** It consist of the essence of your product/service, being also a mix of features like customer experience, speed of service or price. Although it is the most important section, it is also the most difficult one, so it can be completed or changed throughout the years. . Moreover, in the biotechnological companies it can be even more difficult as the product must pass through many quality controls and clinical trials, which would delay the process of settling the value proposition. It is for that reason that in the OLMIBEX example it has been described as “uncertain”.
- d) **Key resources:** It describes the main resources of the company that are going to help in its development and expansion.

- e) **Channels:** It consists of the ways by which the value of the company is going to arrive to the customers, including communication, distribution, etc.
- f) **Revenue streams:** These are the different sources of income of the Start-up.
- g) **Cost Structure:** It covers the fixed and variable cost of the company, used in order to evaluate if the company is viable or not.
- h) **Key activities:** : It consist of the actions which are necessary to carry out the value proposition.
- i) **Customer relationship:** : In this section it is indicated in which way the company is related to its clients.

The point of view of a biotech company regarding the business model is quite different from the one of other industries, as this type of companies in general do not need to focus that much on customer segmentation, relationship or channels of communication., due to the fact that the products pass through many controls, showing then that the new product they are generating is safe for humans and that it has advantages over the existing ones. These parameters are transparent, so the product itself doesn't need to be advertised as the ones of the other sectors (Kappfjell *et al.*, 2016).

A hypothetic Business Model Canvas of OLMIBEX is included below (Figure 8).

Key Partners	Key Activities	Value Proposition	Customer Relationship	Customer Segments
University Biotech Consultants of other sectors External biotech consultants Public institutions NGO (Non-governmental organisations) working in developing countries Funders	Research Innovation Consultancy	Uncertain	Personal but distant	Agro-industrial biotech companies
	Key Resources		Channels	Governments and institutions of developing countries
	Knowledge Funds Patents		Conferences Personal references Internet	
Cost Structure		Revenue Streams		
R&D (Clinical trials) Marketing		Sales Private funding Government		

Figure 8: Business Model Canvas of OLMIBEX

4.2 LEGAL FORM OF THE COMPANY

At the time of founding our biotechnological Start-up, it is essential to choose which legal form must be adopted, as this will establish the capital required to create it, as well as the taxes that we will need to pay for the development of its activity.

The main types are: Individual entrepreneur, Cooperative Society, “Sociedad Anónima” and “Sociedad de Responsabilidad Limitada”(Cámara de Comercio, 2017).

Among all these, the most repeated in biotechnological Start-ups is the “Sociedad de Responsabilidad Limitada” (SL) , due to its easy constitution, which can be carried out either by one person (Unipersonal) or by various associates (Martin, 2016).

One of the main advantages of the SL is the minimum capital required to set it up, in addition to the fact that the partners' liability is restricted to the capital contributed by them.

This is important, because there is a separation between the assets of the company and the personal ones of the associate, in contrast to the form of "Individual entrepreneur", in which if there is a debt with a third entity , it is not necessary to respond with your assets or with those that you do not yet have, but may come to enter your estate, as an inheritance; but simply with the company itself, which is understood as a way of protection of the associates' assets (Cámara de Comercio, 2017).

The partners of our company could be both workers and investors, and the capital would be divided into shares, corresponding to the capital given by each of the associates.

In terms of Social Security, the company bodies, which are the associates that have control of the company (General assembly) and administrators (Figure 9) would have a self-employed regime, while the rest would have a general regime (Infoautónomos, 2017b).

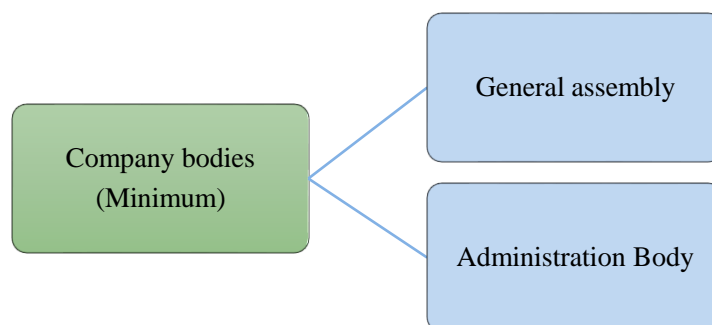


Figure 9: Diagram of the minimum “bodies of the company

a) Minimum capital

A minimum of 3000 euros are required to form a business of this type.

In the case that this money was not available at the moment of the foundation, we can make non-monetary contributions, or set up a limited successive foundation company, which is not recommended in our situation

Non-cash contributions are material objects like office furniture, or in our case, laboratory equipment, which has minimum value of 3000 euros. This value has to be certified by a Notary (Infoautónomos, 2017b).

b) Things that must be done to create a SL

These are the steps that a biotech Start-up as OLMIBEX must follow if it wants to create a SL (Figure 10) (Infoautónomos , 2017a):

1. We must write up the certificate of incorporation and the statutes of the limited company (a lawyer or our Notary can help us in this requirement). The statutes have to be understood as “norms of operation of the society” and they must contain a series of legal forecasts for his inscription in the Mercantile Registry, in order to be valid for third persons. There are certain matters that cannot be regulated in these statutes, things that are regulated by the Pact of partners that complement the statutes of the Society.
2. In this case we must also verify that the denomination we want to give to our society is available. As we have indicated before, we must ask for a certification of denomination to the Central Mercantile Registry (www.rmc.es)
3. Deposit in a bank account the amount corresponding to the capital required to found the society. A certificate has to be requested to the bank.
4. We must go to the Notary, where all the partners will sign the certificate of incorporation that will contain the statutes, and the certification of denomination and the banking certification will be registered in his/her protocol
5. With the certificate of incorporation signed and stamped, we must ask for a provisional CIF to the tax office completing the 036 model.
6. In the following 30 days, it will be necessary to pay the Tax of Transmissions and Legal Transactions. Once this tax has been paid, we will resort to the Mercantile Registry of the

province in which the company has been domiciled for its inscription, obtaining then the final CIF.

7. Finally, the last thing to do will be the Social Security procedures.

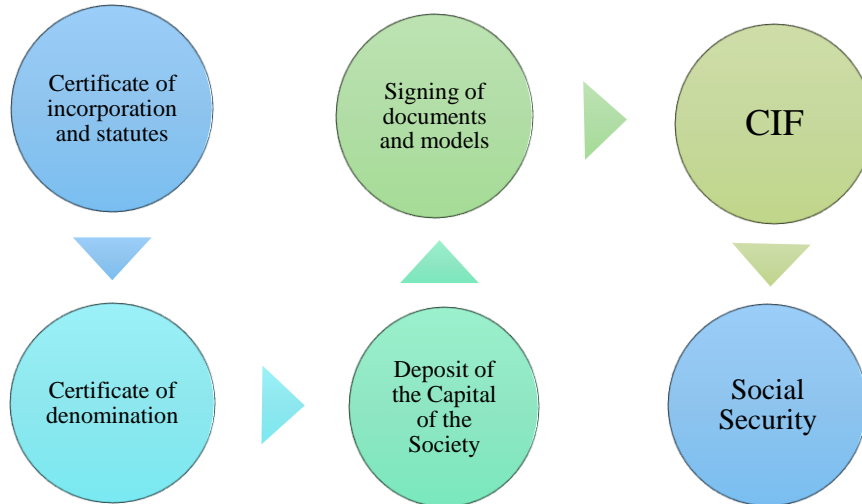


Figure 10: Diagram which represents the steps to create a private limited company

4.3 SHAREHOLDERS AGREEMENT

To invest in a technological company of fast growth as a Biotech Start-up also implies that the investors need to trust on the entrepreneurs and believe that they will work hard to bring the process to a successful conclusion.

Sometimes, all the founders of a business do not continue in the adventure until the end, which can negatively affect the rest of founders of the startup, as well as those investors who have relied on that team of entrepreneurs (Townsend, 2016).

It is for this reason that it is fundamental to sign a pact of shareholders that establishes the relation between all, having a balance between the protection of the investors and the excessive control of the entrepreneurs. In it, there are fixed mechanisms to guarantee that the entrepreneurs do not leave the company, so that in the case they do it, their march would not have negative consequences to the business (Legalvision, 2013). It is also possible to include protecting clauses in the statutes of the company in order to protect the interests of the founders (Annex 1).

There are some responsibilities that can be included in the agreement as for example the obligation of permanence, competition (not to work in a company that supposes a competition for ours in a term of X years) or exclusive obligation. In the case you do not follow correctly this agreement,

a fine can be imposed or for example, as the company “The crowd angel” does, make these entrepreneurs sell their shares for one euro (The crowd angel, 2018).

Another method that is used more and more, mainly in Silicon Valley, is Vesting, a legal mechanism of protection that assures the permanence of the foundation partners or of the employees who have shares of the Start-up. It consists mainly of the fact that the acquisition of a certain package of shares is determined on permanence or the fulfilment of some objectives, so instead of receiving all the shares that would correspond to the entrepreneur, a “calendar” is established to receive progressively these shares (The crowd angel, 2018).

Each Company can do it its own way, but the usual thing is to establish terms of four years and divide the percentage of shares based on time. For instance, in the case of OLMIBEX, with four founders owning each one 25% of the company, if one of them wants to leave the company after the second year, he/she would only receive half of that 25%. At some organizations, instead of fixing terms per year, they do it monthly although the first year is considered as non-severable, that is to say that any partner would have access to any pack of shares until he/she has been part of the company at least 365 days.

4.4 FINANCING

Having a good idea or project is not good enough to success in the bioeconomics area, as it is essential to raise funds, in order to carry out with the sold of our product. Owing to the fact that our company is a biotech one, this quantity of capital needed increases, not only for the product itself, but also because of the regulatory controls that must be performed. Due to the general unfamiliarity with business and management of scientist, it is essential to know which sources of financing are available and which are the best ones in each case (Ford and Nelsen, 2014).

It is said that the process of raising funds is very similar to the one of looking for grants for a research project (Ford and Nelsen, 2014). In addition to consider which is the best option of finance your company, it must be studied which products and companies are in the market in order to have a trendy one. Furthermore, the way to produce it and the marketing areas are crucial to success (ASEBIO, 2014).

Usually, when entrepreneurs search for financing in order to develop their project, they tend to look for it at the banks, as it is the traditional way of obtaining big quantities of money. However, the economic crisis of the last decade has made this way of financing a difficult one to obtain, not just because of the high bank interest rate needed to pay back, but also because the biotech Start-

ups need much more money than the one which the banks, as investors, may offer them (Ford and Nelsen, 2014). As a consequence, the funding rounds emerge as an alternative.

It consists of obtaining capital through the investors, which means that new partners would enter in the company, having part of the social capital of the business, therefore, part of its control. In return, the investors, in addition to the money, will give to the entrepreneur's advice based on their experience to make the biotech Start-up success. It is recommended to do these funding rounds when some capital is needed to begin the Start-up, when a new product or service is released to the market, in the expansion of new markets or when the company is in a bad financial situation, although there are much more circumstances in which it can be applied (Business in fact, 2016).

At the beginning, to start the economic activity, money usually comes from the own funders of the Company and from FFF "family, friends and fools", people with a close relationship with the entrepreneurs. If this money was not enough, there are other options as for example Business angels or Venture capital. Crowdfunding is also an option to obtain money, although due to the high quantity of capital needed for biotech companies (Ford and Nelsen, 2014),

a) Business Angels

They usually are businessman/woman who are experts in the sector of the companies they support, being more than just somebody who gives money to the company, but also a person who is going to help the entrepreneurs to achieve the goals proposed (Ford and Nelsen, 2014).

It is important to take into account that they participate in this project with its own money, which is very different from other methods as financial institutions, pension funds, university funds, or a variety of other sources (Ramadani, 2009).

b) Venture Capital

On the other hand, this type of financing consists of the temporal and minority participation of a Venture capital company as an external investor, which helps the Start-up giving it money in exchange of its participation in its social capital (Ford and Nelsen, 2014).

It is different from the Business Angels due to the fact that the venture capital is not a businessman/woman, it is a financial entity which uses the money of its partners or other companies in order to invest in Start-ups or other companies which are emerging (Peavler, 2017).

During the last years, the number of Venture capital companies which invest in life-sciences Start-ups has been reduced owing to the fact that they prefer to invest in companies which are already developed instead of risking their money with the new-creation ones. Many venture capital

companies create their own businesses making them independent from others, trusting in their scientific and management staff (Ford and Nelsen, 2014).

Series of Funding Rounds

There are different designations of each series according to the stage of investment in the company (Table 4) (Schenk, 2015; Foundation ViCe, 2017):

- The first funding round's stage would be Seed Capital, which consist of the money needed to start the activity of the company, not having any significant income as the product or service is still in development. The capital in this stage is usually from the founders of the Start-up, from FFF (Family, friends and fools) or from small Business Angels (Figure 11) .
- The A series (Fist stage) is characterised by the fact that is the first time the Start-up is opened to external investors, as Business angels with a high capital or private financing (Venture capital and others) .
- The B series (Second stage) is produced when the Start-up is profitable and it is starting to expand and increase the earnings.
- The C series, also called third stage or Grow capital, is the one in which the business is already growing and expanding
- Finally, the series of Private Equity (Mezzanine) would be an extra stage extra in which the business has a difficulty or it requires a huge inversion.

Table 4 : Funding rounds' inversion and characteristics (Schenk, 2015)

	INVERSION	CHARACTERISTICS
SEED CAPITAL	-	<ul style="list-style-type: none"> • Beginning of the activity • Development of the products • No big incomes
A (FIRST STAGE)	<5m. €	<ul style="list-style-type: none"> • There are incomes but no profits • First time that the company is opened to external investors • Preferential shares
B (SECOND STAGE)	5-20 m.€	<ul style="list-style-type: none"> • The company is progressing in its project • Higher valuation of the business
GROW CAPITAL	20-250 m.€	<ul style="list-style-type: none"> • Growth • Expansion
PRIVATE EQUITY	>250 m.€	<ul style="list-style-type: none"> • Mezzaine capital • Bankruptcy • Other investments

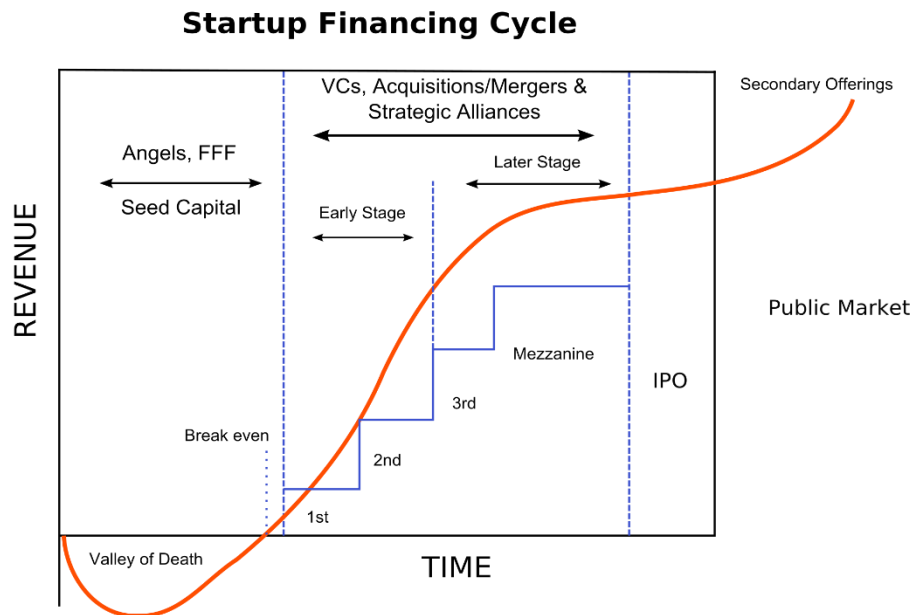


Figure 11: Start-up's Financing cycle (Oppong, 2012)

4.5 PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

Biotech Start-ups are mainly focused on innovation and lead to the market new technologies which can be very useful in medicine, food industry, agriculture, etc. These inventions need to be protected from the use of other companies/institutions due to the fact that a big quantity of money has been invested for its research, being patents the main legal method for protecting the intellectual property in biotechnology (Archana K, 2013).

A patent is an *exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem* (WIPO, 2018a) Patents can, therefore, prevent people who are not authorized from making, using, offering for sale, selling or importing the patented invention.

This exclusive right of operation has a series of limitations (Clarke Modet & Co, 2018c) :

- a) **Time limitation:** The patent as a legal way of protection has a validity of 20 years from the date of presentation, after that time it will be of public dominion.
- b) **Geographic limitation:** The right is only confined to the national territory of the country where the patent has been asked for (in the case of a national patent).

For the concession of a patent there are three requirements (Oficina Española de Patentes y Marcas, 2017):

1. **Novelty:** Everything that has not been previously in the state of the technique.
2. **Inventive activity:** If the product and/or the technique to patent *are not evident for a person who can be considered as an expert in the area of knowledge of the invention.*
3. **Industrial application:** If the invention can be made or be implanted in some industry, being able to be repeated and to be simulated in the same conditions. In the case of biotech inventions , as they may contain biological material , characterized for being dynamic and changeable , it can be complicated to credit the ability to repeat the same experiments with the same results in other laboratories .

There are different types of patents depending of different criteria (Clarke Modet & Co, 2018b):

a) **By its object:**

- Product patents.
- Patents of procedure.
- Patents of use.
- Patents of combination of Well-known Elements.
- Patents of selection.

b) **By its procedure of concession:**

- National patents.
- Regional patents.
- European patents (with protection in any contracting State of the agreement on the European Patent).
- ARIPO patents (with protection in any contracting State of the Protocol of Harare and the PCT).
- Euroasiatic patents (with protection any other contracting state of the Agreement on the Euroasiatic Patent and of the PCT).
- OAPI. Patents (with protection in any state member of the OAPI and that is a contracting state of PCT).
- PCT requests (it allows to ask for protection for an invention in each one of the signatory states of the International treaty of Patents, by means of an international request).

c) **By its dependency:**

- Independent patents: They do not have any relation between them.
- Dependent patents: There is a partial/complete dependency between the different patents, so it is necessary a concession to all of them for its possible operation.
- Divisional patents: A patent must solve a problem. When a single patent solves several independent problems that unit does not form, it is necessary to divide the patent in several.
- Additional patents: It does not imply the pay of annuities and it does not have any function by itself.
- Complementary certificates of Protection: They are referring to products that need a permission from the Ministry of Health for their operation. Due to the delay of these permissions these certificates were created.

In general, any machine, device and/or procedure can be patented. In the case of biotech patents, these could be or contain biological material, or in the case of procedures, any which transforms, uses or produces any biological material. There will also be included in the patents' protection the biological matter which, although it has existed previously in nature, it has been isolated from its natural habitat or produced artificially, what would include the transgenic plants and animals, in which the protection is not for the plant or the animal, but for the gen which is introduced on them or the technique used to introduce it, which is the essence of the invention. However, discoveries, scientific theories or computer programs, among others, are not patentable (Dopazo, 2017).

In the article 5 of the Patents' Law (Law 24/2015) there are included the restrictions for the patents of biotech inventions (Gobierno de España, 2017):

“1. Inventions whose commercial exploitation would be contrary to public policy or morality, not being regarded as such exploitation of an invention merely because it is prohibited by law or regulation.

In particular, they are not considered patentable under the provisions of the preceding paragraph:

a) Processes for cloning human beings.

b) Processes for modifying the germ line genetic identity of human beings.

c) Uses of human embryos for industrial or commercial purposes.

d) Processes for modifying the genetic identity of animals which are likely to cause them suffering without substantial medical benefit or veterinary to man or animal, and the animals resulting from such processes.

2. Plant varieties and animal breeds. They will, however, patentable inventions relating to plants or animals if the technical feasibility of the invention is not limited to a plant variety or a particular plant or animal.

3. *The essentially biological processes for production of plants or animals. These effects are considered essentially biological processes those consisting entirely of natural phenomena such as crossing or selection.*

The provisions of the previous paragraph shall not affect the patentability of inventions concerning a microbiological or other technical process or a product obtained by these procedures.

4. *Methods of surgical or therapeutic treatment of the human or animal body and diagnostic methods practiced on the human or animal body. This arrangement is not applicable to products, in particular substances or compositions, or inventions of apparatus or instruments for the implementation of such methods.*

5. *The human body at the various stages of its formation and development as well as the simple discovery of one of its elements, including the total or partial sequence of a gene.*

However an isolated element of the human body or otherwise produced by a technical process, including the sequence or partial sequence of a gene element may constitute a patentable invention, even if the structure of that element is identical to of a natural element.

The industrial application of a sequence or partial sequence of a gene must be in the patent application.

6. *A sequence of deoxyribonucleic acid (DNA) without indication of any function.”*

As it can be extracted from the current legislation, it is not forbidden the patentability of an isolated element of the human body provided that artificial techniques have been used to identify it or characterise it, in other words, anything discovered directly in nature. However, something that only happens in the area of biotechnology is that in practice, there are some inventions, as the ones in which genetic engineering is involved, whose innovation can be difficult to differentiate from a sheer discovery, what would make that invention no patentable. In order to prove that it is an invention which has to be patented, the owner of the invention has to spend money and time on this demonstration.

In addition to the fact that patents imply an advantage for the entrepreneur against his/her competitor, the protection of his/her inventions will also suppose that the money invested in research and in developing this invention will come back to the Start-up, while if the patent did not exist, other companies would be able to commercialise it and the owner would not receive any benefit from it. Nonetheless, as it has been indicated previously, this right of protection is not everlasting, that is to say, it has an expiry, what can be caused by different reasons (Clarke Modet & Co, 2018a):

- The period of 20 years (+5 of extension) has been finished.
- Non-payment of the taxes.
- The invention has not been utilised.

- The owner has refused the patent.

In addition to patents, there is another method by which the biotech inventions can be protected legally, the utility model, *an exclusive right granted for an invention, which allows the right holder to prevent others from commercially using the protected invention, without his authorization, for a limited period of time* (WIPO, 2018b).

Utility models protect mainly the inventions which are characterised by :

- a. The form of an object.
- b. A significant technical advantage.

In general, the differences between the utility models and patents are that patents protect an invention which did not exist before, while the utility models protect something that existed before, but it has been improved. Furthermore, the utility models have a shorter length than patents and its requirements for its concession are more lax. With the new law of 24/2015 the inventions which are related to a procedure of with biological material and pharmaceutical substances are not considered as utility models(Oficina Española de Patentes y Marcas, 2017) .

In addition to these ways of protection, there is another one called *Know-how*, which is used usually by biotech companies that offer a service for customers, as it does not protect an invention, but it protects the way something is done. It is the combination of knowledge and activities that are done by a business and that are difficult to imitate by others (Clarke Modet & Co, 2018d).

Applying for an European patent

Imagine that a Start-up with a global vision, as OLMIBEX, develops a biotech invention whose creator wants to protect in Europe to make use of it in these countries. Before doing a request for the protection of the invention, first it must be chosen if it is better an utility model or a patent of invention, excluding other forms as copyright, trade secret, know-how , designs and models or trademarks, as they are not applicable to a biotech invention as for example a transgenic fruit-vegetable. . In this case, it is considered that the best option is to request for a patent Moreover, it is necessary to think if the protection is wanted at European level or in any country in particular, as in that case it could be simpler to just ask for the patent in the national office of that country.

Meanwhile, we also must make an exhaustive research on the internet to make sure that the invention at issue fulfils the novelty requirement. It is recommendable to go to experts in the area of the intellectual property so that they make a Competitive Intelligence Review (ITP in Spanish) that consists of *an analysis in depth of the patents that have been published anywhere in the world and that bear relation to a determined technical question* (Zarol, 2018) In addition to knowing if

an invention is patentable, it also can help to clarify if it is needed to acquire the license of some product/procedure from others or if on the contrary, it is of public dominion.

To apply for the European Patent there are some documents which must be attached (European Patent Office, 2018) :

- *A request for grant*
- *A description of the invention*
- *Claims*: It is the most important part of this application as is the one which establishes and defines the invention extensively.
- *Drawings (if any)*
- *An abstract of the invention.*

Additional tips for the protection of Biotech inventions

- Assignment agreement:** There could be a situation in which the scientist who has been the main researcher in the development of a biotech invention, leaves the company in which he/she has developed this product. If he/she has not signed previously this contract, it can be very difficult to prove that the company has any right on this product, which would also carry time and money. The assignment agreement consists of a pact by which an employee allows to associate to the company any invention that he/she develops while he/she works in this company. The usual thing is that at the time of hiring somebody, this person signs this document, although it is also necessary to know if this person has a previous similar agreement with another company, university, public institution, etc (Meltzer, Marks and McCormick, 2002).
- Start working on its distribution:** It is not recommendable at all to wait for a patent to be granted to begin to look for operating areas of your product and to establish agreements with other companies, as time can go by until the concession is confirmed, which implies a waste of time and money to the entrepreneur. In addition, the specific thing for biotechnological inventions is that the innovation and the creation of new products and/or procedures are such that surely at the moment at which the patent has been given, there are other biotechnological inventions that are better and then therefore, will be more successful, having lost then the opportunity to obtain a great benefit as a consequence of the delay.
- Non-competition and confidentiality agreements:** These contracts allow us to keep as secret the information which we do not want to be public. It is recommendable to establish them with the employees or with the external companies that collaborate with the business or with the future partners of the Start-up.
- Dual role:** A Start-up has to understand the patent as an element which can be used in an offensive way, in order to succeed due to the innovation of the invention, and in a defensive

way, as it avoids that the competitors patent or develop the product, that is why the patent's claims has to explain thoroughly the full extent of the invention, so that the competence cannot use the invention without our permission just adding or modifying a little aspect(Meltzer, Marks and McCormick, 2002).

- e) **Patent pooling:** Nowadays is getting commonest the search of alliances between holders of patents which are complemented to each other, which is denominated as patent polling. This concept consists of establishing an agreement between different proprietors from patents, which are essential to develop a common technology, facilitating therefore the use of all the inventions subscribed to the agreement by each of the signers (Meltzer, Marks and McCormick, 2002).

5. IDIOSINCRASIES OF THE BIOTECHNOLOGICAL SECTOR

The difficulties faced by an entrepreneur when he/she decides to carry out a biotech Start-up could be divided mainly in four areas which are intrinsic to this sector:

1. Capital

In the case of new companies, they require a great amount of capital to begin his activity and/or to produce goods, which is the reason why more and more Start-ups decide to break through in the digital market, owing to the fact that the costs are reduced when not having to rent an office or a building to achieve their activity.

Biotechnological companies present an extra handicap due to the cost that is associated to the biotech products, not only the money that is required in its development or the fixed costs of the company, but everything that includes the production of this type of goods, as could be the previous research , the development of a prototype, the specific tests for a possible consumption or use in plants, animals and/or humans, the constant pursuit to verify that it does not cause any problem, and finally, studies of optimization of the process of creation and improvement of the product, as well as to continue releasing to the market new ideas (Ford and Nelsen, 2014).

It is necessary to remember that we are in a competitive market in which the products and the techniques that are developed are replaced quickly, what implies the fact of “adapt or die”.

It is for that reason that more and more biotechnological companies, those of new creation and the great multinationals, decide to invest great amounts of capital in R&D (Research+Development).

As it has been mentioned previously in the finances section, there are different forms to raise capital to put into operation one Start-up, and choosing them cautiously will do them that our company is a success or all the opposite, an enormous failure.

Not only the type of financing is important, but also the people and/or external societies with which we collaborate are crucial in the process of developing and selling of the product. It is important to have in mind that in the business world, the altruism is visibly lacking (Annex 1) .

Any company or businessman/woman is not going to give his/her money to us if he/she does not see clear that our project can be successful and what is most important, if it is not going to receive a great benefit from itself (Cohen, 2002).

As it has already been mentioned in previous sections, it is important to be flexible with the area of management and with the times of development of our idea/company but always without losing the essence of the product and without turning aside which is our final mission (Hofstrand, 2009).

2. Science

It is the main part of the project and the one in which we have to be more focused and display our knowledge about biotechnology.

Any failure in this aspect can have a fatal outcome at small scale (non-sale of the product, bad reputation of the company, infra valuation of the scientific personnel, etc) as at great scale (decrease in the crops 'production yield in the case of being a vegetal product, animal damage and/or human damage, techniques that used wrongly can have bad consequences for the patients , for instance the formation of teratomas in the use of IPS cells; drugs which can be lethal....) .

We can create a biotechnological Start-up, but if the main product or service that we sell does not make the function that was supposed to have it will not be worthy all the effort that we have done.

What we must have in mind is in which degree is going to be important our creation for the society and which is the best form to get to cover that necessity (Cohen, 2002) .

It is vital to emulate all the authorised protocols and in case in which we are developing a new technique, to establish well all the steps that must be followed, so that it can be reproduced by other laboratories in the case in which it is a success, like techniques as PCR, western Blot, ELISA... which are used in most of biotechnological experiments.

In order to carry out the product in a successful way it is essential to have a group of specialists in biotechnology who develop their activity in an optimal form, working in team and having AS a common objective the success of the company.

At the moment when the human capital of the biotechnological company starts to lose its value, also the company and everything what is going to develop does it too .Furthermore it is very important to have equipment in which the activity of invention and research can be carried out in

the best situation, and in which the condition of sterility and the good procedures are maintained constantly.

The problem that arises from this is the money needed to guarantee these conditions, although at the end it compensates the initial investment as it makes possible to have a safe product and to give a good image to all the possible partners and buyers.

3. Society

This is one of the specific difficulties of the sector, which usually faces a company that develops biotechnological products as for example drugs or goods with a vegetal or animal origin which have been modified genetically to obtain some benefit.

The society is very critic with the biotechnological companies that experiment with animals as they are used as a model in the different researches that are carried out. In addition to the national legislation that establishes the legal conducts for the animal protection in the Real Decree 53/2013 of the BOE (Ministerio de la Presidencia, 2013) , institutions have an internal and external ethical committee which evaluate each experiment and whose refusal avoids that the project continues. . It is necessary to know that these animals are used as models to extend the knowledge in many different areas and to know the effects of a specific drug, avoiding the human experimentation.

In addition to the animal experimentation, there is another trivial topic for society, GMO's (Genetic Modified Organisms). Many organizations spend their time trying to discredit this type of products and the companies that produce and sell it.

The main organization in charge of these critics is Greenpeace, alleging as the main reason that there is a generalized ignorance from the scientific world on the consequences that these GMO can have for the health of the consumer and the environment. In addition it exposes diverse reasons for which the GMO are something to avoid. One of these reasons is that the genetic contamination could be produced if there are two crops from one specie, one wild type and the other one modified genetically, fact which usually does not happen as these are separate. Moreover it exists a strong legislation and an exhaustive control of GMO crops (Greenpeace, no date b).

They mention that there are some products in which transgenic maize or soybean has been used to produce them, and this is not detailed in the label. These foods are as healthy as their "natural" equivalent and the modification has been done just to increase the productivity and to resist environmental conditions that could reduce the agricultural production (Greenpeace, no date a).

Another organization who also criticizes the use of transgenics is GMO awareness, a page Web with registered tradename exclusively dedicated to present/display the disadvantages of the transgenics, remarking the risks of the production of GMOs, and promoting ecological food.

The risks that they include are based mainly on opinions of the authors, methods which are no-updated (maintain that the only form of doing a gene modification or an insertion is randomly , they do not contemplate the directed mutagenesis) or on articles in which a concrete failure has been produced , and the authors that write in the webpage generalise this situation to all the experiments This page mentions that the risks of the GMO existence are: Increase in Food Allergies, Unintended harm to other organisms, Corporate Patents Control Nations, Parallel Increase in Autism.... (GMO awareness, 2013).

The main problem of this kind of webs is the great number of fans they have. GMO awareness has an amount of 51300 subscribers, which indicates that these people are interested in this subject and the worse thing, they believe everything what it is discussed there and collaborate in the diffusion of critics against the GMOs, causing that the rest of the society has a negative position against this type of products and is scared to consume them.

Reading the information of these websites what is extracted it is that its main preoccupation is the control of the food and agricultural industry of multinationals, not considering that this genetic improvement can be beneficial for many consumers.

Instead of trying to look for disadvantages the GMO, they would have to pay attention also to the costs associated to research and the process of development of a biotech product cost, which cannot be assumed by small companies and that is the reason why they must sell the patent to greater companies that are the ones which can invest in producing and distributing these transgenic products. Reducing the times of patenting and validating the product we will achieve the reduction of the costs and thus there would be more small companies that have access to this market.

4. Time

Time is also a problem in the biotechnological sector (Annex 1), owing to the years that it can pass from the moment you create something until a real product reaches the market, as it has to be taken into account the time spent in research and development, quality controls, preclinical and clinical analysis in the case of drugs, external controls, etc. This is an grievance compared to the Start-ups of the other sectors, which can sell their products in shortest time, causing them to get benefits earlier, facilitating its expansion and its growth, while the biotech Start-ups often spend many years to reach that state of expansion.

What's more, due to the great innovation that biotechnology entails, and the amount of research centres and public and private entities which discover and develop new methods and products in the areas covered by this science, it arises the problem that once a company has bring to the market a new invention, another entity may develop a better product, so the new invention has to be commercialised faster to get profit from it. However, as discussed in the section of Protection of biotechnological inventions, it is also essential to patent the invention in order to have the monopoly of its use for a period of time, although its granting may be obtained in a few years later (Meltzer, Marks and McCormick, 2002). This fact creates a double bind for the biotech entrepreneur, having to decide whether if he/she prefers to commercialize the invention, even if the patent has not been granted, or just wait for the concession to be given, thus losing the opportunity to get a profit from it in the meantime, only having advantage from the patent for a few years and running the risk that another company develops another better invention during this time, not obtaining then any substantial earning.

A good option would be to ask for a Competitive Intelligence Review before applying for the patent of the invention, which would contribute to show any problem before a possible rejection of the patent's grant. If the review is positive, it allows us to start to make use of the invention and commercialise it without having to wait for the grant.

6. CONCLUSION

To start a biotech Start-up, as it has been seen throughout this final project, is an arduous process, not just because of the difficulties of creating a business itself, but also for the idiosyncrasies of the biotechnology sector which cause that many Start-ups do not have success and end up being dissolved.

There are some steps that are essential in order to found a Biotech Start-up, for instance the detailed drafting of a **Business Plan**, made not only to mark the route guidance of the company itself, but also for the investors, to show them that the project is cost effective and that the money that they are going to spend in the company is going to provide them big benefits. Also, the choice of the **legal form** of our business, which must be chosen mainly according to its minimum capital requirement and of its taxation, being the model of private limited company the favourite among the entrepreneurs of the sector. In addition, there is a document, the **partners' agreement**, which must be written in order to avoid misunderstandings that may occur between the founding partners, or between the founders and the investors, being this an element of legal protection against the leavings of the company's partners, giving stability to the company and confidence to the institutions and to the people who are financing the Start-up. Furthermore, the **sources of funding** for our business, focusing mainly on Business Angels and Venture Capital firms, through financing rounds, which can give the capital injection needed at different stages of the Start-up. Finally, a biotech Start-up usually needs **protection of its inventions**, being the patent the most used in the biotech industry to ensure the monopoly of use of a product/procedure during 20 years (plus 5 years of extension), and making possible to recover the money invested in research and patent's protection during the development of the invention.

In addition to these steps and obviously, **science**, there are other elements that are key for a biotechnological Start-up to succeed. First, the **Management** team, which, as explained previously, is essential to obtain good results. This group, usually constituted by the founders of the company, has to be able to adapt to the market and know in advance what customers want, being capable to end up with an idea completely different from the initial one. This idea would also include workers, which should be committed to the idea of the company and make the most of themselves. On the other hand, it is also advisable to establish limits, rights and obligations of permanence or exclusivity between partners, investors and employees, reducing then the impact on the business if one of them resigns.

Another important factor is the **prediction of the future**. Once the market has been studied, it is not difficult to know what will be successful in a range of 5 years, having to focus not only on making what will be in trend, but improve it, develop alternatives, or seek new avenues of distribution for making our company different from the others. It is also necessary to be up-to-

date with competitors, as well as to follow their strategies and alliances with other companies, in order to anticipate the movements of the other businesses that may be a threat to the success of our company. **Continuous academic training** is also crucial for a biotechnological Start-up to succeed. In addition to the State of the art, it is also fundamental to know about business and management to face all the economy concepts that will be found during the life of the Start-up.

All these *keys to success* have been summarised in the following diagram (Figure 10).

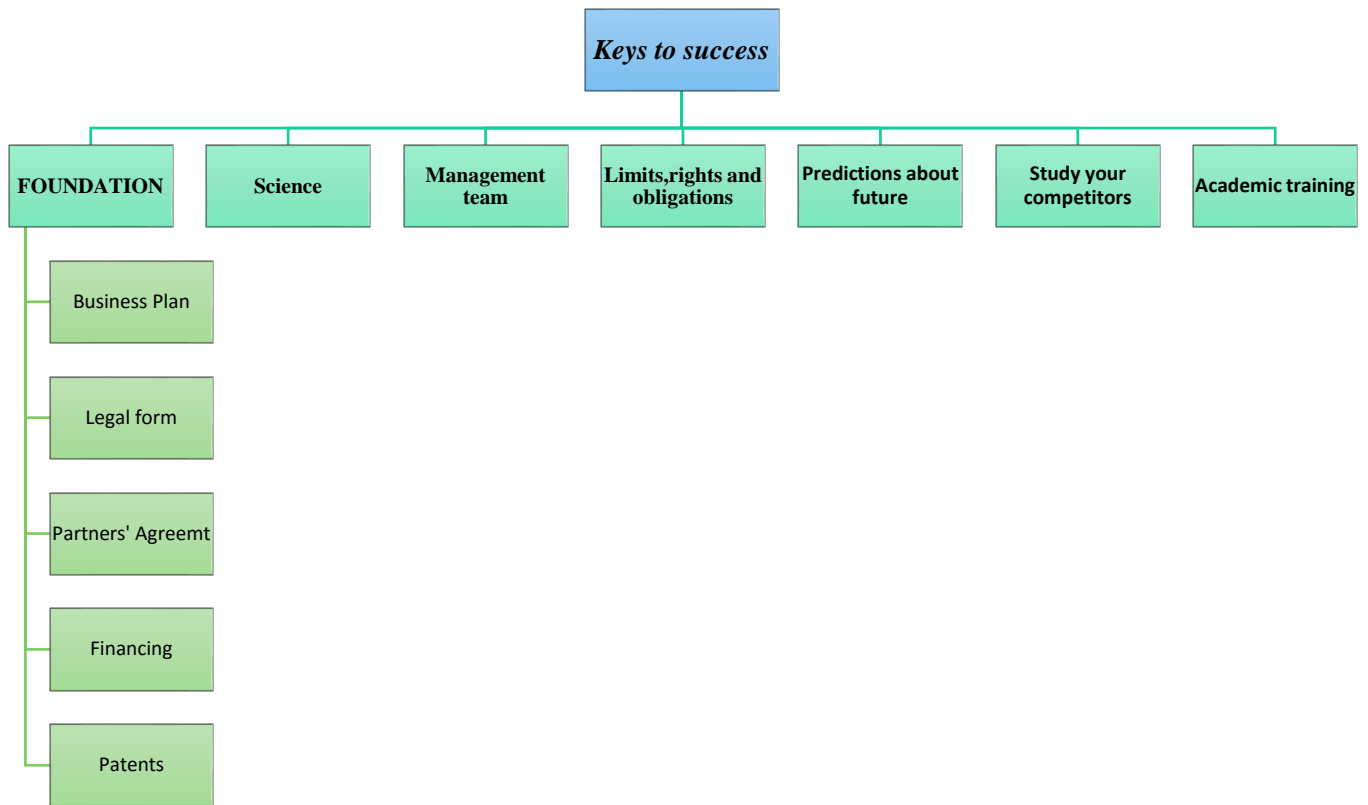


Figure 12: Diagram of the keys to success in creating a biotechnological Start-up

With these tips, combined with dedication, effort and entrepreneurial spirit, you will have all the elements to be able to create your biotechnological Start-up and be successful.

Javier Olmos Becerra

June, 2018

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ANNEX 1

INTERVIEW WITH AN EXPERT

ANNEX 1: INTERVIEW WITH AN EXPERT

Manuel Pérez Alonso has a PhD in Biology and he is the professor of Genetics at the University of Valencia. Moreover, he has founded 9 biotechnology companies, the first in 1998 called *Sistemas genómicos*, continuing with successful Start-ups as *IMEGEN* (Institute of Genomic Medicine) or as a collaborative partner in *Bemygene*, which is the first company in Spain that is specialized in the Prevention of cancer and genetic counselling. In addition to this, he has also been the President of Bioval (Association of companies and organizations that constitute the Bioregion of the Valencian Community) from 2012 to 2018. This interview with an expert was done in order to obtain information about the foundation of biotech Start-ups.

1. From your point of view, what is a Start-up?

A Start-up is a business which has been recently created and that is founded in order to develop a new concept, although the concept may not be completely new, at least the novelty of the company is a requisite, as everything starts from zero.

2. How did the idea of Imegen emerged?

Imegen emerged as an idea to restart a career that was truncated in our evolution. , I say “our” as I was not the only promoter of that company, we were two people the ones who owned the company founded in 1998, dedicating on it 12 years of our lives. When the vicissitudes of fate, and a few strategic mistakes that we made, led to an appropriation of the company by our legal advisor, we were in 2009 without company and we then decided that if we could create a company once, we would be able to do it again , so we tried to restart our business, and that was the reason of the foundation of IMEGEN.

3. IMEGEN was “born” in the initial years of the crisis. How did this affect to the Start-up?

We thought that it would affect it , but what we find is that , as Genomics is a sector that is so innovative , that arouses so much interest and with so many applications, we could grow and develop without any problem, despite the economic downturn of the country.

4. What were the main sources of funding for this project?

The main sources of funding were the partners of the previous Company and other investors who wanted to support our Project

5. ¿Which legal form did you choose for IMEGEN?

We decided that IMEGEN would be a *Sociedad de Responsabilidad Limitada (SL)*

6. Did you establish a Partners' Agreement?

What we did was not a partners' agreement, we decided to write down in the statutes some hiperprotecting clauses for the founders.

7. Which difficulties may emerged during the process of entrepreneurship?

As entrepreneurs, the main difficulty is that the entrepreneur has to materialize a product that is useful for potential customers. First you have to find the clients and then do something they want and / or need. That's one thing that has to be concrete, it's not about having an idea and say "I'm going to sell this", which is the typical mistake of the entrepreneur; you must change the chip and have a generic idea that you then have to specify with the client's opinion, and if they do not like it, go back to the laboratory or to the office and modify it to suit the client.

8. In which way are the inventions/techniques of IMEGEN protected?

In IMEGEN, due to the strategy of the company, we chose to protect our techniques by the method of Know-How, as we saw that it was the most profitable option for our business.

9. How is the internal management of IMEGEN?

First of all, it gives a great autonomy to work teams, having their own initiative, their own decision making... There is a very good atmosphere, which promotes the development of inventions and the growth of the company.

10. How has IMEGEN's internationalization process been?

It has been a little bit stumble, developing strategies with similar firms outside Europe, also looking for distributors and having people exclusively dedicated to this, as it is not the same to sell in Spain than doing it in a market such as the European or the global one.

11. Are outside of Spain open to the Spanish biotech Start-ups?

We have observed some initial rejection in some countries due to other Spanish companies because of their strategies, which have caused a repudiation to the "Spain brand", but after that, when we explained what we were doing and our strategy, they saw that our company was different, changing then their opinion about Spanish Start-ups

12. Which do you think is the main mistake of the biotech Start-ups that end in failure?

There is no one in particular, there are two or three. The first would be the excess of optimism, being materialised in the fact that all entrepreneurs, especially the bioentrepreneurs, do some optimistic sales forecasts, being in reality the third or the fourth part of what they initially believe. In addition, during the process, there is an increase of the cost, which the entrepreneur usually has

not taken into account. The second failure would be that, as they believe that their company is very good, they ask too much money to investors, not being aware that they are not an NGO. The third is the one I have mentioned previously about not specifying the product according to the customer.

13. Do you think that the Government supports entrepreneurs enough?

No, in my opinion bioentrepreneurs are misunderstood due to the extra number of complications caused by the increase of the costs, time, etc.

14. What advice would you give to a student who wants to found a biotech Start-up?

First, be realistic. Second, do not start the company on your own, join other people with the same objectives as you and seek for experts who may help you. Finally, surround yourself with people of confidence and maintain a fluid dialogue with the investors.

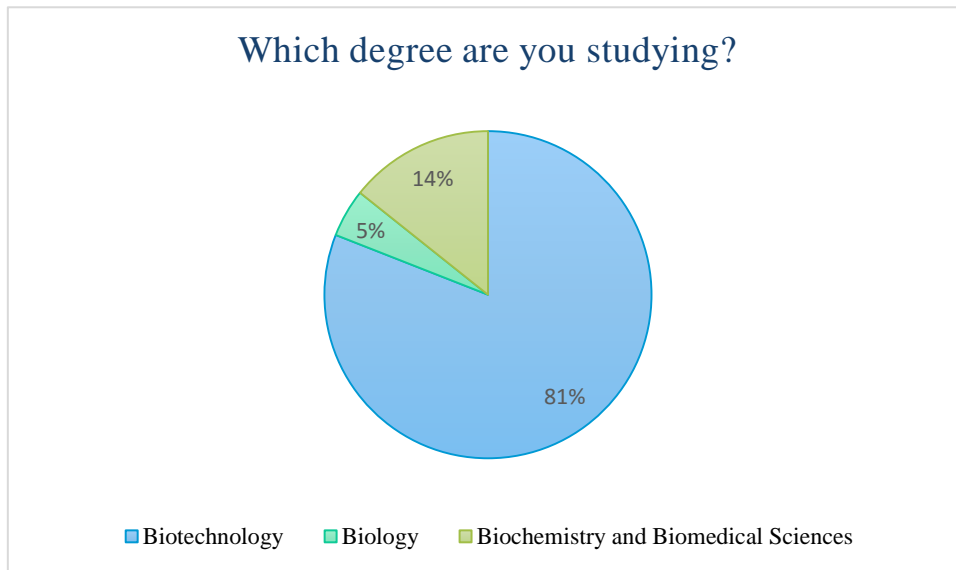
ANNEX 2

SURVEY ON THE INTEREST IN ENTREPRENEURSHIP OF LIFE SCIENCES' STUDENTS

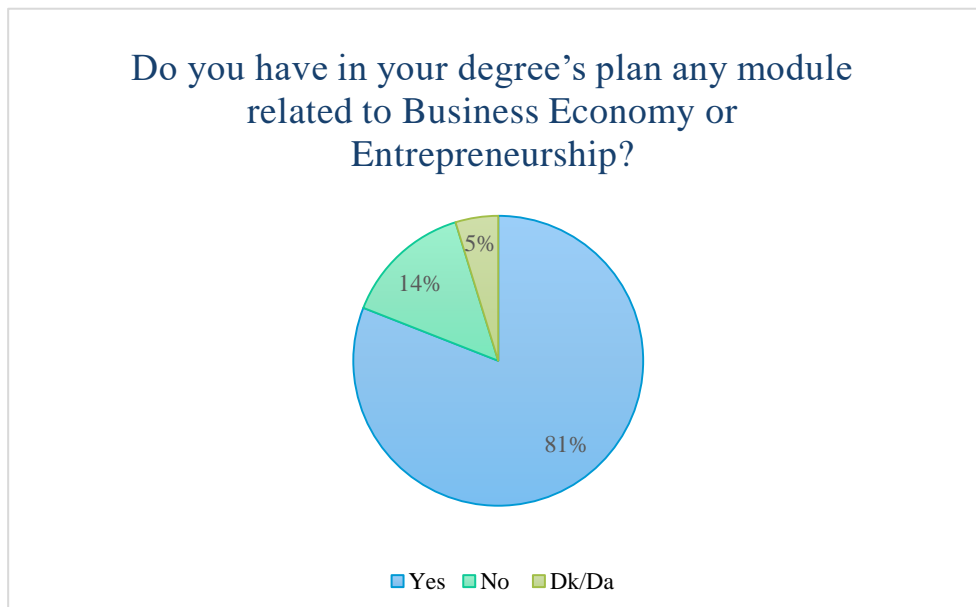
ANNEX 2: SURVEY ON THE INTEREST IN **ENTREPRENEURSHIP OF LIFE SCIENCES' STUDENTS**

These are the graphs made from the answers given by the 63 students of Biotechnology (UPV), Biology (UV), and Biochemistry and Biomedical sciences (UV) who were surveyed through the Google Form's platform.

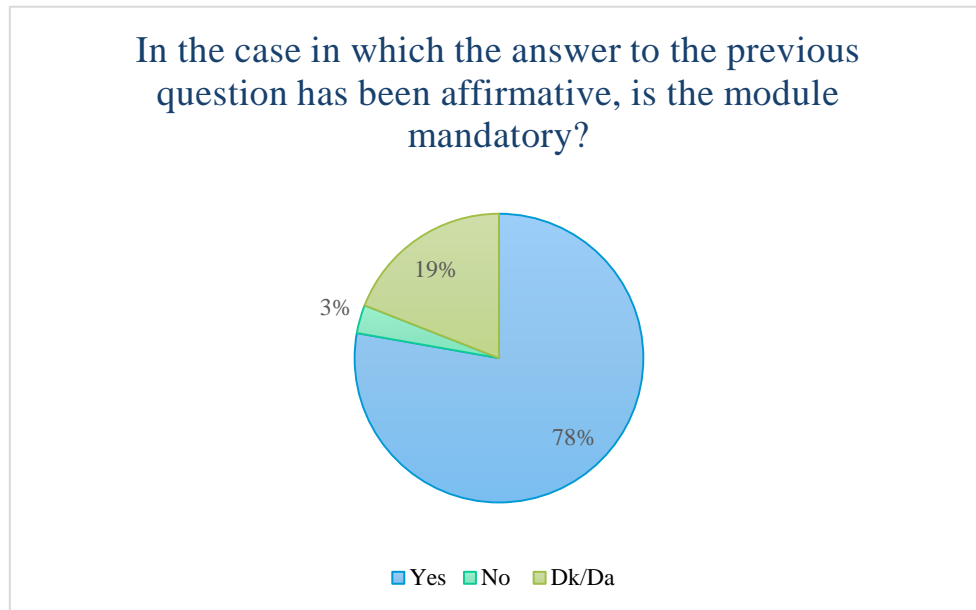
1. Which degree are you studying?



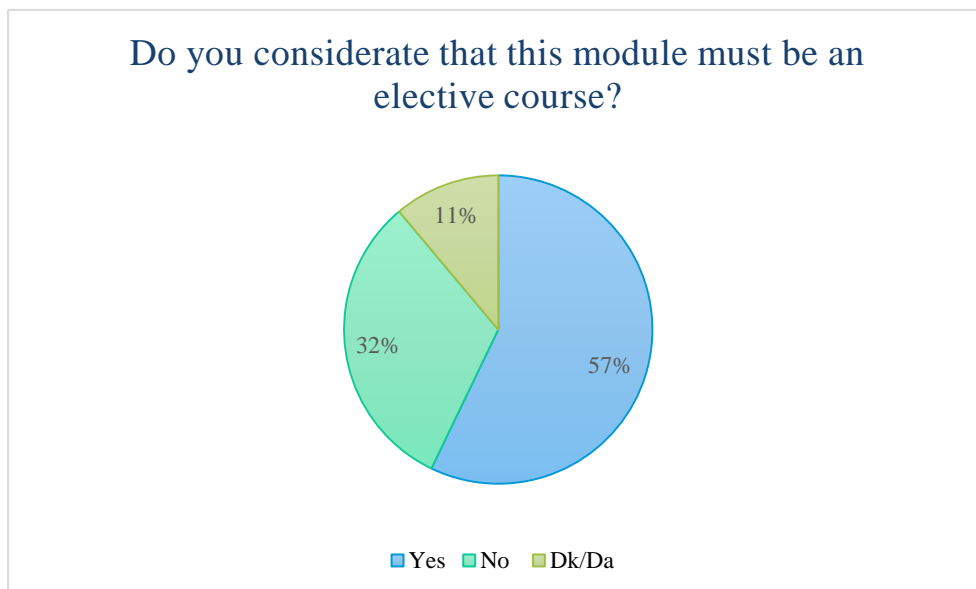
2. Do you have in your degree's plan any module related to Business Economy or Entrepreneurship?



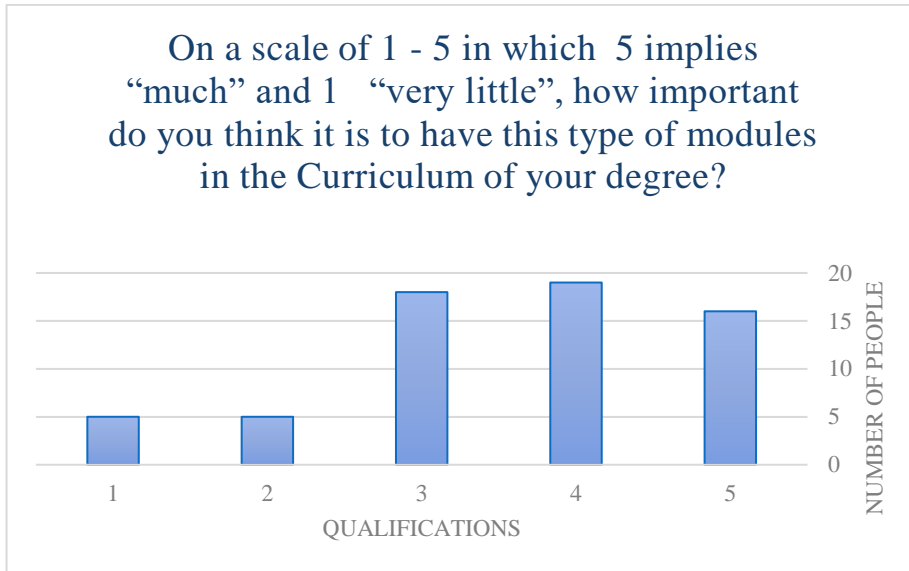
3. In the case in which the answer to the previous question has been affirmative, is the module mandatory?



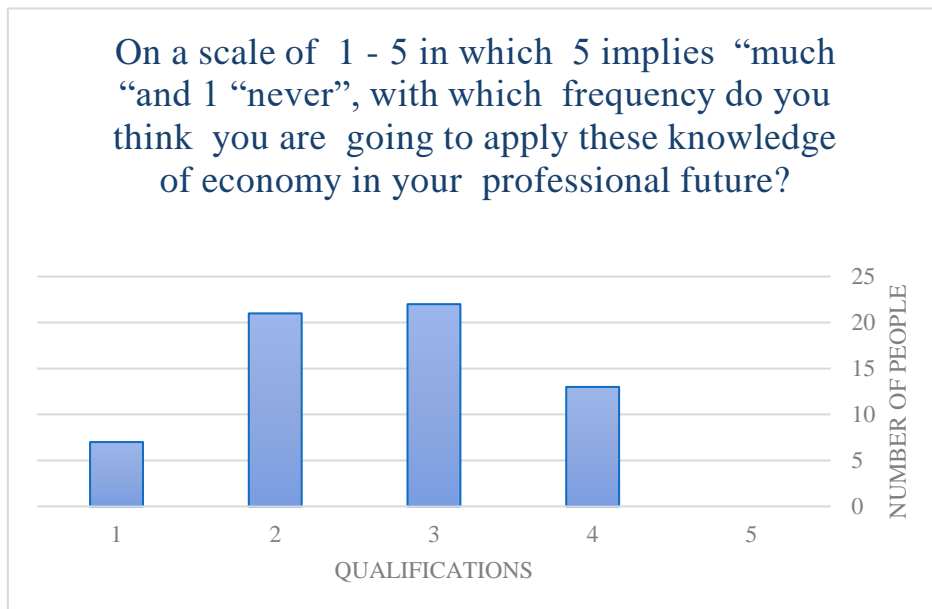
4. Do you considerate that this module must be an elective course?



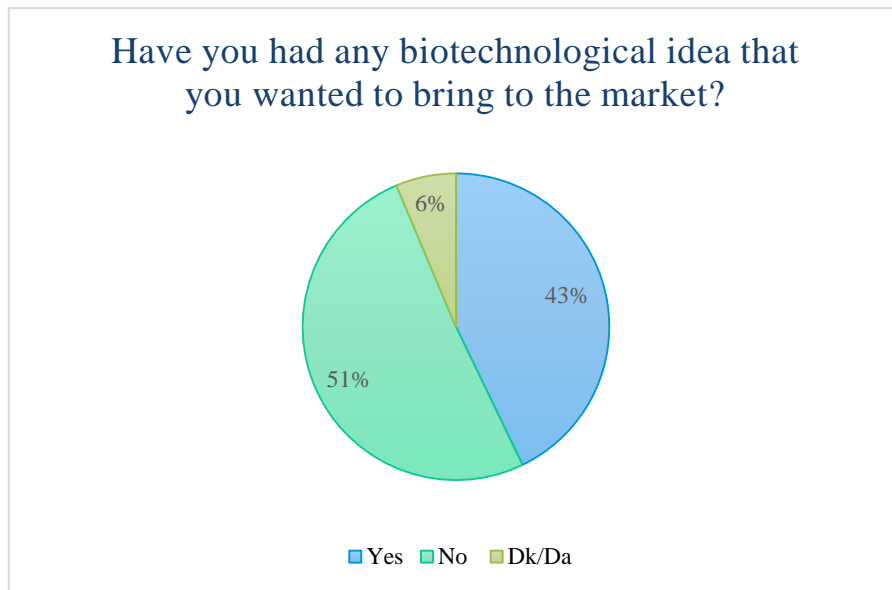
5. On a scale of 1 – 5 in which 5 implies “much” and 1 “very little”, how important do you think it is to have this type of modules in the Curriculum of your degree?



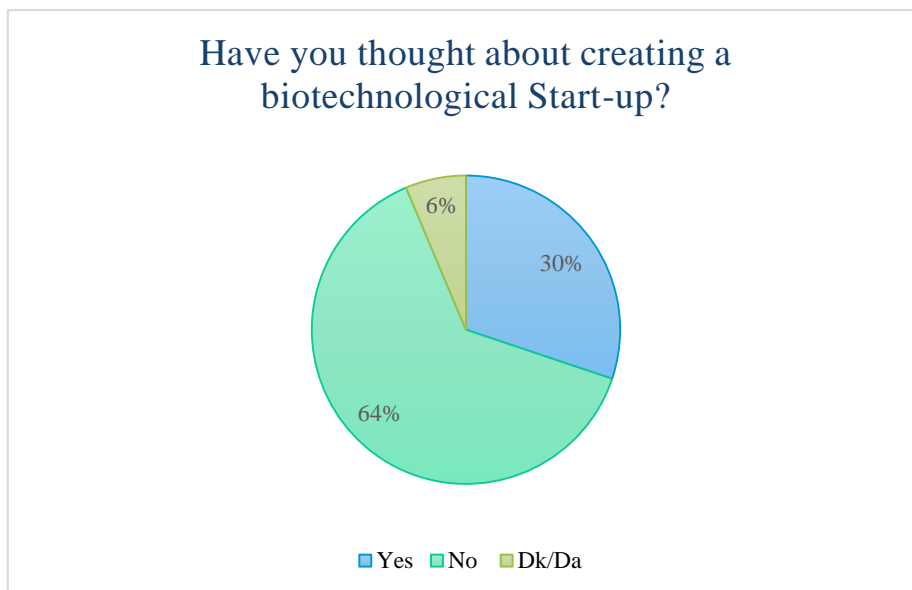
6. On a scale of 1 – 5 in which 5 implies “much” and 1 “never”, with which frequency do you think you are going to apply these knowledge of economy in your professional future?



7. Have you had any biotechnological idea that you wanted to bring to the market?



8. Have you thought about creating a biotechnological Start-up?



9. Do you think that with the knowledge that you have in the area of business and management you would be able to create a Biotech business in the case you had an idea to develop?

