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asebio

Spanish Biotech Industry:

Main Success Stories

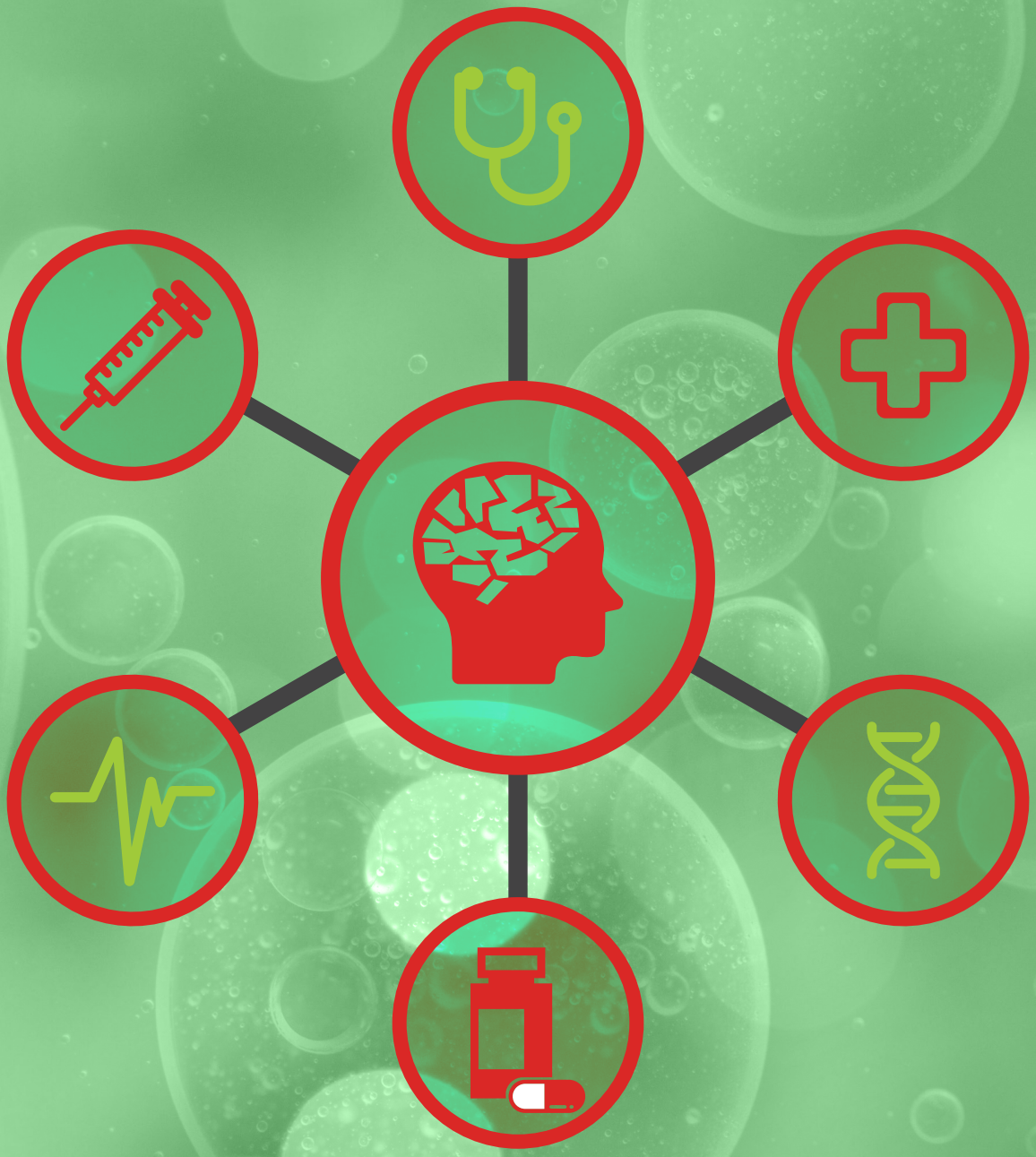

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TABLE OF CONTENTS

1. Introduction 7

2. An overview of the Biotech Industry 11-19

2.0. Summary 12-13
2.1. Research and development 14
2.2. Knowledge generation 15
2.3. Spin-off 15-17
2.4. Investment 18
2.5. Successful exit scenarios 18-19
2.6. Economic Impact 19

3. Main Success Stories (2008-2018) 21-61

3.0. Methodology 23
3.1. Ability Pharmaceuticals 24-25
3.2. AELIX Therapeutics 26-27
3.3. Alcaliber 28-29
3.4. Anaconda Biomed 30-31
3.5. Biopolis 32-33
3.6. Grifols 34-35
3.7. MedLumics 36-37
3.8. Minoryx Therapeutics 38-39
3.9. Mosaic Biomedicals 40-41
3.10. Oryzon Genomics 42-43
3.11. Palobiofarma 44-45
3.12. Peptomyc 46-47
3.13. Pharma Mar 48-49
3.14. Plant Response 50-51
3.15. Progenika 52-53
3.16. Reig Jofre Laboratories 54-55
3.17. Sanifit 56-57
3.18. STAT-Diagnostica 58
3.19. TiGenix 59
3.20. 3P Biopharma 60-61

4. References 62-63

5. Acknowledgments 64

*"**Honesty, passion** for the project and great **resistance** to the challenges and failures that appear during the entrepreneurship process."*

Carles Domènech
AbilityPharma

*"Find **people** with a track record that can easily guide you at a technical and business level. Go to experienced investors"*

José Luis Cabero
AELIX Therapeutics

*"Creating a business will cost a lot of sacrifice and effort. Find something that you will **enjoy**."*

José Antonio de la Puente
Alcaliber

*"To be successful, surround yourself with the right **people**."*

Ofir Arad
Anaconda Biomed

*"Identify your **client** type and once you have, dedicate yourself completely to them."*

Daniel Ramón Vidal
Biopolis

*"Be **realistic** and honest about your idea. An idea should be focused on solving a real and specific clinical problem, instead of trying to find some problem able to be solved with it."*

Jose Terencio
Grifols

*"Be realistic and always seek to maintain **credibility**. Don't commit yourself to do things that you already know you can't achieve."*

Marc Martinell
Minoryx Therapeutics

*"Running a biotech requires a special personality, you should feel comfortable dealing with risk and uncertainty and be a **hard worker**"*

Judit Anido
Mosaic Biomedicals

*"First define your business type, understand the value chain structure and believe in the project. Then, start to build, starting from the 2 basic lines: **science-team and funding**."*

Carlos Buesa
Oryzon Genomics

*"Drug discovery and development can't be learned at university or business school. Find someone that has **experience** in drug discovery in a pharmaceutical industry."*

Julio Castro-Palomino
Palobiofarma

*"The strength of a company is its **team**. Choose your team in an intelligent way. Find people with different experience, knowledge and points of view."*

Laura Soucek
Peptomyc

*"Keep going and keep an open mind! A biotech project is a long-distance race and during this travel you will need to be open to **innovation** and potential **collaborations** in a fast-paced environment."*

Carmen Eibe
PharmaMar

*"Conduct a market study to demonstrate that there is an **unmet need**, choose good **partners**, define your **business model** and focus on the areas, in which you can be the best."*

Eduardo Quemada
PlantResponse

*"Don't rush. Before becoming an entrepreneur, you must **train yourself** both technically and from a business perspective."*

Antonio Martínez
Progenika Biopharma

*"Have a good team of people with **energy and tenacity** that believe in the product and wish to fight for it."*

Isabel Amat
ReigJofre

"You miss 100% of the shots you don't take. You won't succeed, if you don't **try**."

Joan Perelló
Sanifit

*"You should have the **desire** and the **drive** to create something valuable"*

Dámaso Molero
3P Biopharmaceuticals

1

Introduction

The Spanish biotech sector is relatively young in comparison with the industry world leaders. Nonetheless, Spain has been able to develop a dynamic biotech ecosystem by combining all the necessary ingredients to foster the emergence of new projects, their development and growth into success cases.

The Spanish biotech ecosystem comprises large university hospitals where cutting-edge research is carried out; important research centres and technology centres where basic and applied projects are carried out; universities that ensure education, research and the transfer of the results of such research; small spin-off and start-up companies led by entrepreneurs who develop their pipeline through the funds raised with venture capital investors and public funds; and larger companies result of different growth models and with commercial capabilities, among other key stakeholders.

This report aims to be a proof of the good state of health of the Spanish biotech industry and a demonstration of its degree of maturity. The number of scientific publications, the patents generated, the spin-offs founded, the closed financial rounds and the liquidity events that have taken place in the last years are a clear sign of this reality.

This report describes a total of 20 success cases of the Biotechnology Sector in Spain in the last 10 years. These success stories have been carefully selected by a cross-sectorial jury representing the main stakeholders involved in the Spanish Biotech sector. The selection process has intentionally included success cases from the main three application areas of biotechnology: namely red (healthcare), green (agriculture and food industry) and white biotechnology (industrial uses).

Although it may sound obvious, it is necessary to say that the aforementioned successes would not have been possible without hours and hours of work, effort and sacrifice of researchers, entrepreneurs and their teams. All of us who work in, or with, this particular industry, are well aware of the passion the professionals of the Spanish biotech industry devote to their projects in a tough environment of high uncertainty, long development timelines and high investment requirement. For each project that succeeded and met its maximum potential, many failed or did not reach their expectations. But this does not mean that the experience was not worth the try. The experience gained by the teams that failed to accomplish success, the lessons they learnt, were recycled back into the industry. In fact, these early failures provided some of the building blocks for the success stories shown in this report.

This report aims to highlight some of the success stories of the Spanish biotech industry during the last years. Being a short list of 20 success stories, many other could not be included even though they probably were also high quality success cases. Nonetheless we believe that this selection of 20 cases will help all of you, specially those who are foreigners and wish to gain insight into what is going on in the Spanish biotech industry, some insight into the opportunities Spain can offer to international investors and industrial partners looking for collaborations.

Josep Lluís Falcó
Founder and CEO
GENESIS Biomed

Berta Borràs
Consultant
GENESIS Biomed

Jorge Alvar Villegas
Director for Infrastructure, Health and ICT
ICEX SPAIN TRADE AND INVESTMENT

Ion Arocena Vélez
General Manager
Spanish Bioindustry Association-ASEBIO

2

An overview of the Biotech Industry

2. SUMMARY

6. ECONOMIC IMPACT

€617 M
Invested by Spanish Biotech companies in internal R&D expenditure in 2016

0.7%
of the Spanish GDP came from dedicated Biotech companies

100
Products or services launched in 2017

5. EXITS

2
Acquisitions of Spanish Biotech companies in January 2018 by Big Companies

8
License agreements between biotech Spanish companies and big corporations in 2017

€93 M
Invested by Venture Capital in Spanish Biotech companies in 2017

9
of the 42 companies listed in the MAB are Biotech or Pharma

4. INVESTMENT

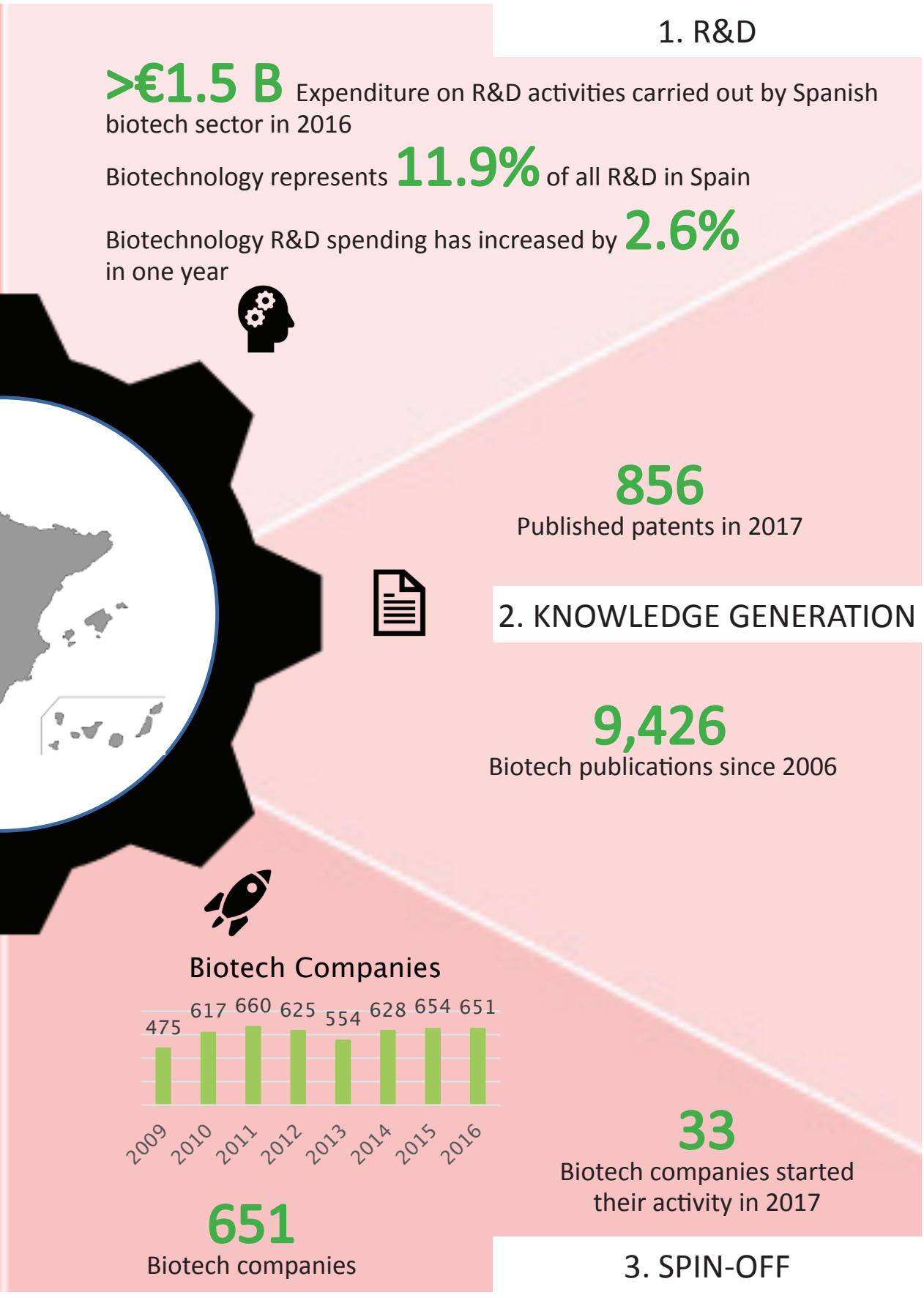


Figure 1. An overview of the Spanish Biotech Industry (Summary)

2.1. RESEARCH AND DEVELOPMENT

Spanish R&D Expenditure in 2016

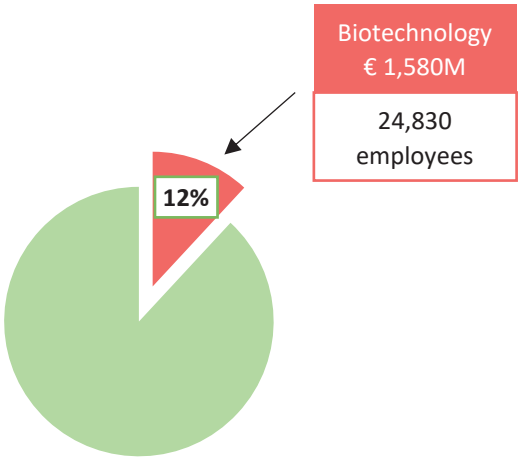


Figure 2. Spanish R&D Expenditure in Biotechnology and number of employees dedicated to this activity[1].

National expenditure in R&D activities related to Biotechnology reached **1,580 million euros in 2016**, an increase of 2.6% compared to 2015. Biotechnology represented 11.9% of total R&D expenditure in Spain.

The total number of people engaged in R&D activities in Biotechnology increased by 2.3% in 2016 (as compared to 2015) to reach **24,830**. This figure represented 12.1% of the total personnel employed in R&D activities. Among them, 56.5% were women.

Results of Spain in Horizon 2020

According to the Centre for the Development of Industrial Technology (CDTI), Spanish entities obtained 2,816 million euros in H2020 grants between 2014 and 2017. In the ranking of countries, Spain occupied the **fourth position** with a 10% return of the total EU-28 budget, after Germany, the United Kingdom and France. By theme, the best Spanish results in H2020 were obtained in the **"SME Instrument"** (with 18.3% of the EU-28) and in "Nanotechnologies, Advanced Materials, **Biotechnology** and Advanced Manufacturing and Processing" (with 14.5% of the EU-28).

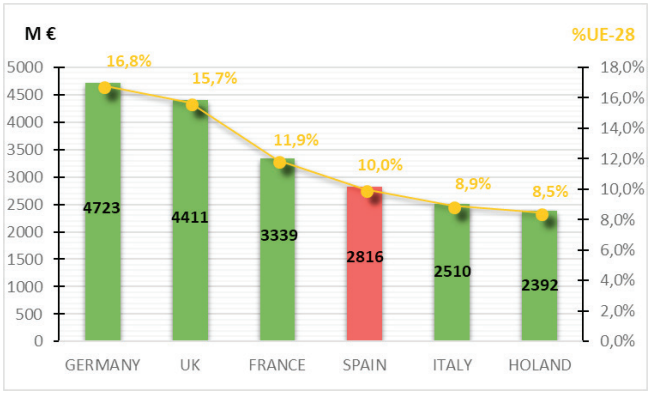


Figure 3. Economic return obtained by the top 6 European countries in Horizon 2020 (2014-2017)[2].

Within the territorial distribution of funding by autonomous communities, Catalonia achieved the best return (29.5%), followed by Madrid (24.9%) and the Basque Country (14.6%).

2.2. KNOWLEDGE GENERATION

Patents and Publications in Biotechnology

In 2017, **856 Patents** were published in the biotechnology sector (66% corresponded to applications and 34% to granted patents). Most of the patent applications were filed at European Patent Office (EPO) and Patent Cooperation Treaty (PCT), representing 69%, followed by applications via Oficina Española de Patentes y Marcas (OEPM) and the United States Patent and Trademark Office (USPTO). Regarding the granted patents, the greater percentage was represented by those processed through EPO, consisting of 46% of the total.

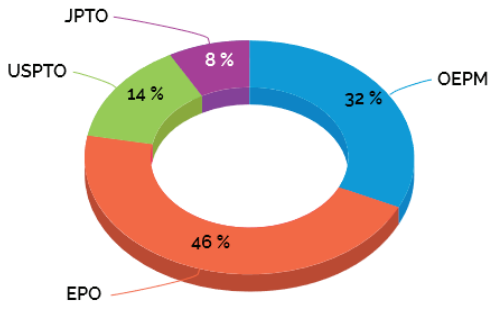


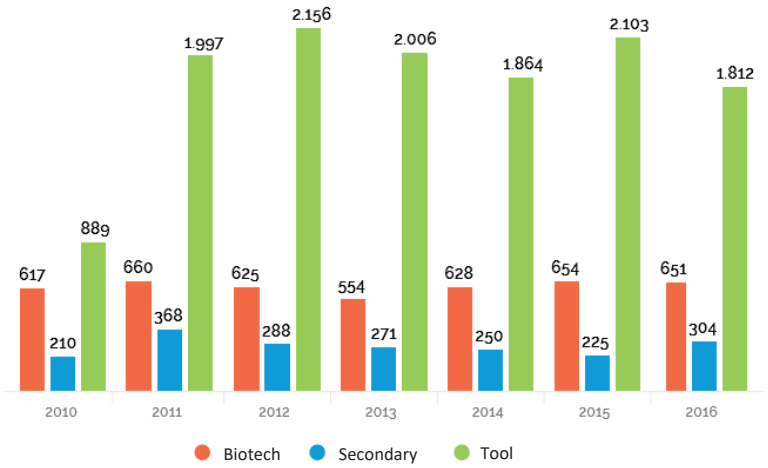
Figure 4. Granted Patents in Biotechnology (2017) [3]

In 2015, the Spanish scientific production, with 78,740 documents in SCOPUS and 58,130 in WOS (web of science), was ranked eleventh position in the world ranking and fifth position in Europe. The impact factor was 4.53% (SCOPUS) for Agriculture and Biological Science, 3.32% in Biochemistry, Genetics and Molecular Biology and 3.77 in Immunology and Microbiology[4]. Regarding **scientific publications in biotechnology**, 9,426 papers were published from 2006 to 2015. International collaboration in scientific production was 46.5%, with the US, France, Germany, Netherlands, United Kingdom and Italy being the principal collaborators[5].

2.3. SPIN-OFF

Biotechnology companies in Spain

According to the report "Key Indicators on Biotechnology" published by OCDE, Spain is the 3rd country in the OCDE region with a significant number of Biotech companies[6]. In 2016, **651 companies** had biotechnology as their main activity, 304 as a second activity and 1,812 used Biotech processes as a tool. 37 companies associated with ASEBIO have international operations, being present in 41 markets across the 5 continents. The total number of international subsidiaries reached 133 in 2016.



As of 2016, 651 Spanish companies' primary focus was biotechnology

Figure 5. Evolution of the number of companies with biotechnological activities (2010-2016)[7].

Table 1. Percentage of companies according to biotechnology area of application (2016). Some companies have more than one area of application, what makes the total differ from 100%.

TYPE OF COMPANY	HUMAN HEALTH	FOOD INDUSTRY	AGRICULTURE & FORESTRY	ANIMAL HEALTH & AQUACULTURE	ENVIRON-MENT	INDUSTRY
Biotech	66.8%	23.5%	17.4%	20.8%	10.1%	11.3%
Secondary	40.6%	32.5%	23.4%	15.4%	17.8%	14%
Tool	6.7%	79.2%	9.7%	5.6%	3.4%	3.6%

Human Health and Food Industry form the leading sectors of Biotech companies, with 66.8% and 23.5% respectively. Companies of the Food Industry are the most frequent users of biotechnology as a tool[7].

Distribution of biotechnology companies and main bioregions in Spain

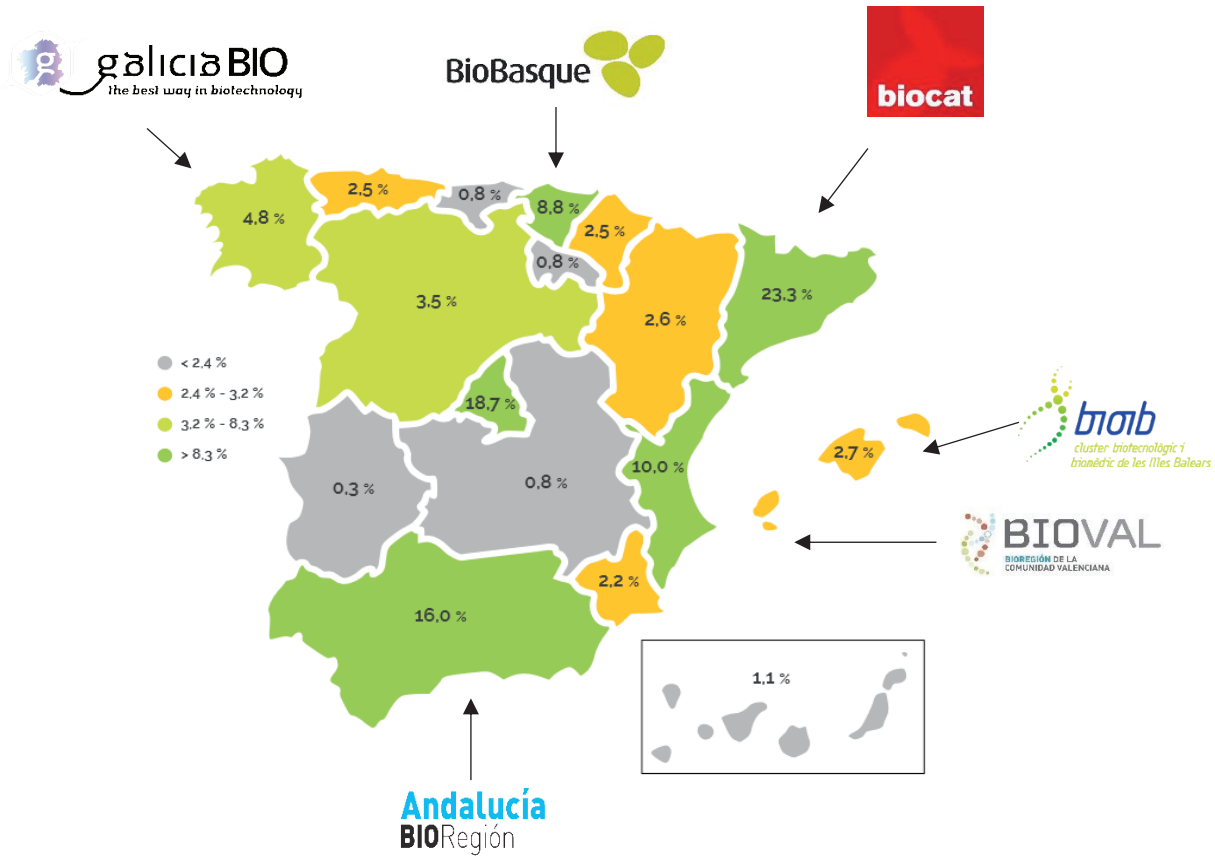


Figure 6. Distribution of biotechnology companies by autonomous regions in Spain (2017).

Catalonia is the autonomous region with the largest number of companies dedicated to biotechnology (23.3%), followed by Madrid (18.7%), Andalusia (16.0%), Valencia (10%) and the Basque Country (8.8%)[7].

33 biotechnology companies started their activity in 2017. 7 companies were established in Andalusia, 7 in the Basque Country and 7 in Catalonia. These autonomous communities were followed in number by Galicia (4), Asturias (2), Madrid (2), Castilla la Mancha (1), Castilla y León (1), Navarra (1) and Cantabria (1)[7].

Bioclusters act as strategic agents and catalysts in the construction of the respective Bioregion's health and life sciences ecosystem. They encourage all the stakeholders of the BioRegion (companies, research groups and entities, hospitals and innovation support structures) to transform knowledge and technology into economic growth and to create a social impact. The most important Bioregions in Spain are Biocat, Andalucía BIORegión, BIOVAL, BioBasque, GaliciaBIO and BIOIB.

2.4. INVESTMENT

Private Investment in 2017

27 investment rounds took place in 2017, with a final size of more than 93 million euros. The average amount per round was 3.4 million euros. Among these, the biggest ones were MedLumics (that reached 34.4 million euros) and Anaconda Biomed (15 million euros). International investors participated in both cases[7].

The top Spanish venture capital companies specialized in the biotechnology sector (Caixa Capital Risc, YSIOS Capital, Inveready, Clave Mayor, CRB, HealthEquity, Columbus Venture Partners, IUCT Emprén and ALTA Life Sciences) invested 30 million euros in biotech companies in 2017. In addition, more than 46 million euros were committed for future investments. Moreover, 7 new investment funds have recently been launched, with the following target size: Alta Life Sciences (175 million euros[8]), Asabys Partners (60 million euros[9]), Uninvest (40 million euros[10]), Inveready Biotech III (25 million euros[11]), Inkemia Fond-ICO Global (10 million euros[12]), Navarra Tech Transfer Fund (with 4.1 million euros[13]) and Nina Capital.

In 2017, there was a total foreign investment amount of €93 M in Biotech companies. National venture capital investment reached €30 M and an additional sum of €46 M was committed for the future.

The Alternative Stock Market (Mercado Alternativo Bursátil - MAB), that started operations in 2009, opened new funding opportunities to Biotech SMEs. As of the end of August 2018, 9 of the 42 companies listed on the MAB belonged to the Pharmaceutical and Biotechnology sector[14]. One of these companies is Atrys Health, which began 2018 with a capital increase of 9.2 million euros[15].

2.5. SUCCESSFUL EXIT SCENARIOS

According to the ASEBIO Annual Report, **100 products or services** were launched into the market by members of ASEBIO in 2017[7].

Mergers and Acquisitions:

In 2017, the biopharmaceutical company Biofabri acquired 100% of the company Probiosearch and 80% of the company Bialactis Biotech. Archer Daniels Midland (ADM) acquired 90% of Biopolis' shares. Inkemia acquired 100% of the companies Otec Riera and Laboratorio Micro-Bios. Grifols acquired 49% of the capital of the company Access Biologicals for 47.9 million euros[7].

In January 2018, QIAGEN entered into agreement to acquire STAT-Dx for 154 million euros[16]. In July 2018, the Japanese big pharma Takeda acquired TiGenix for 520 million euros[0]. In August 2018, Grifols expanded its plasma collection network by acquiring 24 Biotest centres in the United States[18]. In the same month, Almirall acquired Allergan's US dermatology portfolio in a deal worth up to 650 million dollars[19].

8 licensee agreements were closed by Spanish biotechnology companies in 2017:

Table 2. Licensee agreements closed in 2017

COMPANY	TECHNOLOGY	LICENCED TO
InKemia IUCT Group[20]	Results of an R+D project that develops natural products with biological activity in patients affected by Myotonic dystrophy type 1 (MD1)	MyoGem
Bionure[21]	Bionure's main candidates' rights in the field of otolaryngology	Spiral Therapeutics
Bionaturis[22]	Leishmaniasis vaccine for Argentina and Paraguay	Biotandil
ALGENEX[23]	CRISBIO™ technology for recombinant proteins manufacturing	BIOKIT
PharmaMar[24]	License agreement for Lurbinectedina in Australia, New Zealand and several Asian countries	Specialised Therapeutics Asia
SOM Biotech[25]	Worldwide license for SOM Biotech SOM0226 compound against amyloidosis	Corino Therapeutics
PharmaMar[26]	Licensing and commercialization agreement for Zepsyre® in South Korea	Boryung Pharm
Biosearch Life[27]	"Lactobacillus fermentum LC40 ®" strain	Nestlé

2.6. ECONOMIC IMPACT

ASEBIO estimated the total economic impact of biotechnology companies on the whole Spanish economy, both directly and indirectly. Companies mainly dedicated to biotechnology exceeded 7,300 million euros of gross domestic product (GDP) and 108,000 employees in 2016, which represented around 0.7% of the national total, generating a tax income of 2,600 million euros for Public Administrations[28].

In 2016, the impact of biotechnology companies was 0.7% of the Spanish GDP

Companies that carry out biotechnological activities had an economic impact of 7.8% of the Spanish GDP and more than 847,000 jobs, in 2016. The contribution of these companies to the public finances exceeds 25,000 million euros annually[7].

The R&D expenditure of Spanish biotechnology companies was 617 million euros in 2016[7].

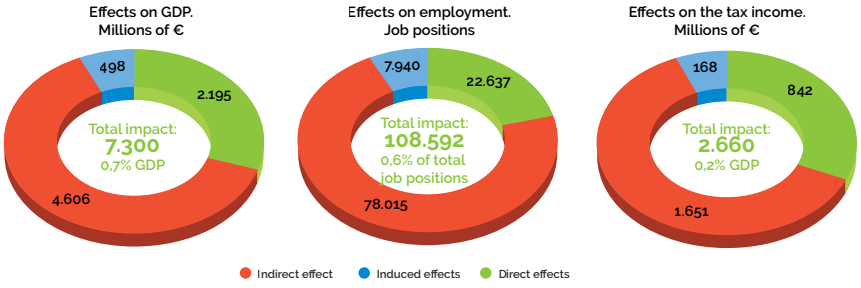


Figure 7: Summary of Biotech companies' economic impact in 2016[7].

3

Main Success Stories (2008 - 2018)

3.1. METHODOLOGY

The methodology to select the biotechnology companies to be included in this report has been the following:

Through a complete bibliographic search, ASEBIO and GENESIS Biomed made a list of the 50 most relevant Spanish biotechnology companies. The criteria for company selection were: company's main activities and relevant milestones achieved in the last 10 years (financing rounds, licenses, acquisitions, turnover increase, listing on stock exchanges, etc.). According to their main biotechnology activity, the companies were classified as red biotechnology (health), white biotechnology (industrial) or green biotechnology (agri-food and environmental technology).

A panel of 10 experts in biotechnology participated in the selection of the 20 success cases. Among them, there were professionals from venture capital firms, technology transfer offices, consultants, CEOs, managers and enterpreneurs (see page 60 for more details). They were given a list of 50 success cases and the latest milestone achieved by each company, in order that they could score each company. Any conflicts of interest were taken into account and if an expert had any relation with a company, he or she did not score this company. In order to have all types of biotechnology represented in this report, at least one company of each type had to be selected. GENESIS Biomed gathered all the evaluations and calculated the average score for each company. At the end, a list of 20 selected Spanish companies was obtained.

GENESIS Biomed interviewed one reperesentative of each selected company and made a summary of the most relevant information. In the case of MedLumics, STAT-Diagnostica and TiGenix, there was no interview and the content was acquired from the Internet. Each summary includes an image that represents company's sector:


Red Biotechnology (Biopharma)


Green Biotechnology (Agri-food)


White Biotechnology (Industrial)

Overview of the methodology

1. Bibliographic search and definition of an initial list with 50 companies

2. Selection of an Expert Committee. First contact.

3. Voting process. The experts select a final list of 20 firms.

4. Interview with one representative of each company

ABILITY PHARMA is in Phase 2 Trials in Europe with ABTL0812 in Patients with Lung or Endometrial Cancer – US IND

CARLES DOMENECH
Chief Executive Officer
carles.domenech@abilitypharma.com
www.abilitypharma.com

COMPANY TYPE
Therapeutics

TECHNOLOGY
Developing first-in-class molecules causing autophagy for cancer treatment.

FOUNDERS
Carles Domènech and Jordi Espadaler

FOUNDED
2009, Cerdanyola del Vallès (Barcelona)

RAISED
€6 M

INVESTORS
Inveready, BA, private investors, SODENA.

TECHNOLOGY

Ability Pharmaceuticals is a clinical-stage biopharmaceutical company committed to increasing the survival of patients with advanced cancer by developing highly innovative drugs, capable of removing tumour cells through autophagy. The company has two discovery programs for solid tumours and a Pipeline of 3 compounds:

- **ABTL0812** A first-in-class molecule, orally administered that binds to the nuclear receptors PPARα/γ causing PI3K/Akt/mTOR pathway inhibition. In Phase 2 clinical trials for lung and endometrial cancer.
- **ABTL0814**
- **ABTL0815**

In preclinical development for solid tumours.

The first drug candidate ABTL0812 (a new lead compound) is currently in phase 2 clinical trials as first-line therapy for endometrial and lung cancer in leading hospitals of France and Spain.

COMPANY HISTORY

FDA Approval of Phase 1/2 Trial of ABTL0812 for Patients with Pancreatic Cancer has been announced in 2018. This will allow the entray of the company into the US market.

Ability Pharmaceuticals was established in 2009 with headquarters in Cerdanyola del Vallès, Barcelona. The company licensed the molecules from a spin-off company of the University of the Balearic Islands and obtained the seed capital needed for its preclinical validation. An experienced, honest and enthusiastic management team was built. The financing to carry out the preclinical regulatory development was raised in 2012 and a successful regulatory strategy was defined. This allowed the approval of the clinical trials in Spain and France, as well as obtaining orphan drug designations by the FDA and EMA for pancreatic and the paediatric cancer neuroblastoma. The first clinical trial was conducted in Barcelona and a license agreement was signed with the US company SciClone for the development and commercialization of ABTL0812 in China, in May 2016. A wide network of KOLs was built in Europe and in the United States. The phase 2 clinical trial (80 patients) with ABTL0812 for endometrial and lung cancer was approved in September 2016.

BUSINESS MODEL

Due to the high R&D investment needed for drug development, especially in the phase 3 clinical trial, the objective of AbilityPharma is to maximize the value of their ABTL0812 project, completing the clinical proof of concept (phase 2), before licensing it to a multinational pharmaceutical company with enough human and economic resources to continue with the candidate's development. The company is constantly updating Big Pharma companies with their latest clinical results and milestones.

"The objective is to license ABTL0812 to a multinational company in the next 2 years"

KEY CHALLENGES & ACHIEVEMENTS

"The business potential of the project was validated with the signing of a license agreement with the NASDAQ-listed US company SciClone to develop and market ABTL0812 in China, Hong Kong, Taiwan, Macao and Vietnam, for a value of more than $20 M."

According to Carles, the major success of AbilityPharma has been taking the drug candidate ABTL0812 to the clinic: from its acquisition from the university, carrying out its preclinical development, to successfully beginning of the international phase 2 clinical trial in first-class European oncology hospitals, such as Vall d'Hebron Institut of Oncology (VHIO), Institut Català d'Oncologia (ICO), Hospital Clinic Valencia and Hospital Virgen del Rocío in Spain; and Institut Gustave Roussy, Centre Léon Bérard and Institut Paoli-Calmettes in France; as well as getting the IND approved by the US FDA. Carles says: "My major challenge has been to build a first-line, high-performance professional team, experienced and enthusiastic, and aimed to succeed. This has been the key factor for the project's success."

GROWTH AND FUNDING STRATEGY

The 1st company investment was made by the founders and government funds from CDTI (Government of Spain) and ACCIO (Government of Catalonia). Inveready, shareholders, business angels and private investors participated in additional financing.

In 2012, the company closed the first €1 M financing.

FUTURE OF BIOTECHNOLOGY

"Biomedical research will continue to be the most important field in the coming years"

Carles considers that research should go towards: 1) transforming cancer into a non-lethal chronic disease during the next 10 years, 2) slowing down aging 3) developing artificial organs, 4) research of new antibiotics, and 5) neurodegenerative diseases.

SOME ADVICE FOR FUTURE ENTREPRENEURS

- **"Honesty, passion for the project and great resistance to the challenges and failures that appear during the entrepreneurship process."**
- **"Forecast which will be the potential market of your product when it will be launched."**
- **"Surround yourself with an excellent team of managers, advisors and mentors."**

AELIX THERAPEUTICS enrolled the First Patient in its Initial Therapeutic HIV Vaccine Clinical Trial, in September 2017

JOSE LUIS CABERO
Chief Executive Officer
jlcabero@aelixtherapeutics.com
www.aelixtherapeutics.com

COMPANY TYPE
Therapeutics

FOUNDED
November 2015, Barcelona

TECHNOLOGY
Therapeutic HIV vaccines

RAISED
€11.5 M

FOUNDERS
Christian Brander, Bonaventura Clotet, Jordi Naval

INVESTORS
YSIOS Capital, Johnson & Johnson Innovation, Caixa Capital Risc

TECHNOLOGY

AELIX Therapeutics is developing novel vaccines to contribute towards a functional cure for HIV infection. Their technology is based on HTI, discovered by Dr Christian Brander, CSO of the company, and co-workers. They observed that T-cell responses to certain HIV regions were enriched in individuals with enhanced natural control of their HIV-infection. The HTI immunogen brings these beneficial regions together in a single vaccine immunogen sequence. The immunogen is being delivered to the body in multiple viral and non-viral vectors (DNA plasmids, a Modified-Virus-Ankara vector (MVA), and a Chimpanzee-Adenovirus (ChAd)). The main AELIX vaccine's goal is that HIV patients can eradicate or control the virus, without having to take antiretroviral treatments on a daily or weekly basis.

HTI immunogen: a new therapeutic vaccine against HIV. Currently on phase I-II clinical trial.

COMPANY HISTORY

In 2016, AELIX completed a Series A funding round of €11.5 M ($12.7 M), led by YSIOS Capital and also supported by Johnson & Johnson Innovation and Caixa Capital Risc.

AELIX Therapeutics is a spin-off of HIVACAT, a Catalan public-private consortium conducting cutting-edge research in the field of AIDS. The HIVACAT programme, which aims to develop strategies to prevent and cure HIV and AIDS, is led by IrsiCaixa Aids Research Institute and the Infectious Diseases and AIDS Unit of the Hospital Clínic of Barcelona. It also has the ongoing support of Fundació "la Caixa", Generalitat of Catalonia, Fundació Clínic and Fundació Glòria Soler, and, historically, the pharmaceutical company ESTEVE. The HIVACAT consortium licensed the HTI technology to AELIX Therapeutics for its global development and commercialization.

BUSINESS MODEL

The company has the traditional business model of biotech companies: creating value, reducing risks and capturing the interest of a powerful player in the pharmaceutical world that can continue the development in the pivotal phases, Phases II and III, and bring the technology to the market.

AELIX Therapeutics' business is to create value, reduce risks and attract big Pharma.

KEY CHALLENGES & ACHIEVEMENTS

"Having started the first study in HIV-infected subjects has been a great progress. There are not many therapeutics vaccines that have reached this stage."

AELIX Therapeutics' key challenges are of a technical nature, in particular, to manufacture three vectors under Good Manufacturing Practice conditions. This requires the intervention of 3 different Contract Manufacturing Organizations: one in the UK, one in Germany and one in Italy. Their challenge is triple because they need to develop 3 different Investigational Medicinal Product Dossiers. Jose Luis says that the differential factor of AELIX is that they have been able to assemble a very strong management team. He explains that they have been able to move forward in a relatively short time, thanks to their global network of highly competent consultants and service providers. They are conducting a clinical trial and they are planning to start another one in early 2019.

GROWTH AND FUNDING STRATEGY

The operating funds of AELIX Therapeutics come essentially from the Series A Funding Round of 11.5 million euros completed at the beginning of 2016, led by YSIOS Capital, Johnson & Johnson Innovation and Caixa Capital Risk. During the first-half of 2018, they received some supportive public funding.

AELIX is essentially supported by private investment.

FUTURE OF BIOTECHNOLOGY

"Some hot technologies are CRISPR and CAR-T."

These are good times for biotechnology and biomedicine. We have reached a pivotal moment, where technologies that began to be developed in the '80s or '90s are mature enough to treat disease that were untreatable 20 years ago, like liquid tumours and hepatitis C. "In the coming 5-15 years, we will see significant advances for the treatment of solid tumours, neurodegenerative diseases, and challenging infectious diseases", says Jose Luis.

SOME ADVICE FOR FUTURE ENTREPRENEURS

- **"Find people with a track record that can easily guide you at a technical and business level. Go to experienced investors."**
- **"Look for good science, good intellectual property, good team, and good financing."**

ALCALIBER

ALCALIBER, a World Leader in the Narcotic Industry

JOSE ANTONIO DE LA PUENTE
Chief Executive Officer
delapuente@alcaliber.com
www.alcaliber.com

COMPANY TYPE
Agricultural biotechnology company

FOUNDED
1973, Madrid

TECHNOLOGY
Production of alkaloids from Narcotic Raw Material.

SALES
€61 M (in 2016)

FOUNDER
Juan Abelló Pascual

NET PROFIT
€10 M (in 2016)

TECHNOLOGY

Alcaliber cultivates opium poppy plants and manufactures its concentrate (CPS) (rich in Morphine, Thebaine, Codeine and Oripavine), as well as alkaloid extracts. With these concentrates, Alcaliber manufactures Active Ingredients (like morphine, codeine, diacetylmorphine…) for pharmaceutical use (mainly used for the production of analgesics) and commercial use. A by-product (the seed of the poppy) can be used in the baking industry. In 2016, Alcaliber became the first company in Spain to be granted a license for growing, producing, manufacturing, importing, exporting, distributing and commercialising cannabis and its products for the pharma industry.

World leader in the production of Morphine and Thebaine.

Alcaliber products are marketed worldwide, and 95% of their production is exported.

COMPANY HISTORY

Currently, Alcaliber is a world leader in the narcotic industry, with a production of 27% of the Morphine and 18% of the Thebaine on a global level.

In the '30s, Abelló Laboratories first applied to import 400kg of Opium. The raw material was mainly imported from India and Turkey. In 1974, it was decided to shift to an integral industry approach and manage the entire production process, ranging from poppy cultivation (*Papaver somniferum*), to production of its derived active pharmaceutical ingredient. Alcaliber, S.A. was established with the aim of guaranteeing the supply of Narcotic Raw Materials through poppy cultivation in Spain and its subsequent extraction of their alkaloids into Concentrate of Poppy Straw (CPS). In 2003, the company's strategy changed to foreign expansion and diversification of products and client countries. In 2010, Alcaliber achieved International GMP Certification.

BUSINESS MODEL

Jose Antonio explains that Alcaliber tries to combine the production of a semi-elaborated product (narcotic raw materials) with the production of a more purified product (active pharmaceutical ingredients). They focus all their R&D activity in the search of products with a higher added value.

Alcaliber strives for excellence and optimization at each stage of the production process, ensuring high quality and competitive products within the Pharma industry.

KEY CHALLENGES & ACHIEVEMENTS

"Alcaliber's major success has been the shift from being a national supplier to being a world leader in the narcotic industry."

"In the company, good investment decisions have been well in advance of market opportunities."

In Jose Antonio's opinion, Alcaliber has become a world leader thanks to their focus on the product (making a high-quality product with a very efficient production system) and client's needs. Their model is based on competitiveness, quality and customer & supplier trust.

Alcaliber's big challenge has been to anticipate the production needs as per the commercial needs.

GROWTH AND FUNDING STRATEGY

Jose Antonio explains that in 1973, the founding partners made their contributions and counted on the support of bank financing. From that moment on, the company has been generating its own resources. Their major clients are: chemical industry, pharmaceutical industry and baking industry. In his opinion, Alcaliber is better than its competitors because they have been able to develop products of higher added value, thanks to their research in the following areas: agriculture, chemical processes and business development.

The research carried out at Alcaliber has enabled them to differentiate the company from their competitors by developing products of higher value.

FUTURE OF BIOTECHNOLOGY

"Biotechnology tools evolve quickly, and companies have to constantly stay updated."

According to Jose Antonio, Biotechnology is a clear trend in the Pharmaceutical Area, meaning that everyday there are more bioproducts and biopharmaceuticals as a deliverable product to the patient.

SOME ADVICE FOR FUTURE ENTREPRENEUR

- **"Creating a business will cost a lot of sacrifice and effort. Find something that you will enjoy."**
- **"Focus your strategy based on experience in all areas, doing the best in each of the value chains of your company. This will allow you to grow, be profitable and better than your competitors."**

ANACONDA BIOMED closed a €15 M Series A Financing in 2017

OFIR ARAD
Managing director
o.arad@anaconda.bio
www.anaconda.bio

COMPANY TYPE
Medical devices start-up

TECHNOLOGY
Medical device (MD) for the treatment of ischaemic stroke

FOUNDERS
Ofir Arad, Marc Ribó

FOUNDED
April 2015, Sant Cugat del Vallès (Barcelona)

RAISED
> €17 M

INVESTORS
YSIOS Capital, Innogest Capital, Omega Funds and Banco Sabadell

TECHNOLOGY

The product of Anaconda is a next generation catheter to perform mechanical thrombectomies safely and efficiently. It has 2 modalities: one used to navigate (which has the same diameter as the competitor) and a second one, which at the moment of reaching the thrombus is able to open its mouth and aspirate it. In addition, the technology is able to reduce the flow within the cerebral arteries; and currently, there is no device capable of doing so.

The company is developing a medical device (MD) for the treatment of ischaemic stroke, which is capable of extracting thrombi from the brain. Patients eligible to use the device are those who have suffered stroke up to 24h.

COMPANY HISTORY

The first step was to leave the company for which Ofir worked. Taking as an example the start-up ecosystem of Israel, he surrounded himself with the best possible equipment and immediately obtained both public and private financing.

“When you have your own project, you don’t give up as easily as when you have a secure environment.”

Ofir had the idea of applying the existing technology in areas of cardiology to the interventional neurology with a disruptive approach. Although there were already devices for the extraction of ischemic thrombi, none complied with the requirement to adapt its size to that of the artery. In this way, it is possible to interrupt the flow, facilitating the intervention, and also the extraction of the thrombus in its entirety, minimizing the possibility of distal thrombi. According to Ofir, "we were very lucky, because a few days after starting the company, a clinical study was published that shows that thrombectomy, which is the technique we are betting on, is the best treatment for stroke."

BUSINESS MODEL

At the moment, the company is developing the technology (verification and validation studies) and in the future they plan to sell the product to hospitals. A complex system is needed to rapidly treat people with stroke. Therefore, their market will be focused on developed countries that have a correctly working stroke code. Their main markets will be Europe and USA. Within Europe, they plan to start in Germany. Another possibility, which is in the interest of Anaconda investors, is the acquisition of the start-up by a larger company.

The company has a new CEO, Mr. François Salmon, PhD., who has large experience in medical devices companies development strategy.

KEY CHALLENGES & ACHIEVEMENTS

Anaconda's major success has been to close a €15 M Series A Financing, the largest Series A in the history of medical devices in Spain.

Ofir affirms that all milestones have been important for Anaconda. He thinks that they were fast enough to have the technology ready and reach the verification phase. His major difficulty was that he didn't have any training in business or management. He had to adapt himself to some changes: being an entrepreneur, instead of a researcher; and begin working by himself, instead of working for others. He believes that it is a really interesting experience and he recommends it to anyone.

GROWTH AND FUNDING STRATEGY

The company has focused on private financing. Their focus was on funds that were interested in medical devices, not just in the local market, but all over the world. They sought Business Angels in Israel, Switzerland, England, USA, Ireland and Germany. Anaconda put interest too in non-dilutive fundings. Obtaining ENISA, Emplea, EIT Health, Neotec and RETOS grants has brought great value to Anaconda, not only in the financing area. "If the public institutions support you, the project becomes stronger quickly", says Ofir.

"The feedback from investors has always been positive. They exposed the problems that the company had, and the team has tried to correct them."

FUTURE OF BIOTECHNOLOGY

"More research should be made in those cases where there is a device capable of replacing a drug."

In Ofir's opinion, the pharmaceutical and the molecular biotechnology sector are stronger in Spain. Nevertheless, more R&D should be focused on medical devices.

SOME ADVICE FOR FUTURE ENTREPRENEURS

- **"Understand that 100% of 0 is 0%; and that having a small % of something, is more than 0%."**
- **"To be successful, surround yourself with the right people."**
- **"People that failed in other projects, multiply your success rate by 3, and someone that has been successful, multiplies it by 9."**

90% of the Shares of BIOPOLIS were Acquired by the Giant Archer Daniels Midland (ADM)

Daniel Ramón Vidal
Vice-president R&D
Health & Wellness ADM
Daniel.RamonVidal@adm.com
www.biopolis.es

COMPANY TYPE
Microbiology service provider

TECHNOLOGY
Provider of microbial technologies for food companies, pharma, chemical manufacturers, cosmetic industry and energy & renewables

FOUNDERS
Daniel Ramón Vidal

FOUNDED
June 2003, Valencia

TURNOVER (in 2017)
€6.5 M

COMPANY SHARES
90% Archer Daniels Midland (ADM)
10% CSIC

TECHNOLOGY

Biopolis has 4 business units in food and health:

- LIFESEQUENCING. Specialized in massive genomic sequencing, it studies the response of human or animal microbiome and metagenome to different diets and pathologies.
- PROBIOTICS. From sourcing and screening of novel strains to preclinical and clinical evaluation, scale-up and industrial manufacturing of probiotics. Mainly sold to infant nutrition and pharmaceutical companies.
- NOVEL INGREDIENTS. The company uses the preclinical model *C. elegans* for the analysis of novel food and pharmaceutical active ingredients.
- CELL FACTORIES. The core experience is the overproduction of valuable metabolites, such as proteins, specialized sugars and biopolymers.

Biopolis is a research and development company that provides R&D services in the field of microbial biotechnology.

COMPANY HISTORY

"We are where we are thanks to everyday work, having walked in our customer's shoes and having worked collaboratively."

Biopolis was founded in Valencia, as a spin-off company of the Higher Council for Scientific Research (CSIC), together with three industrial partners: CAPSA, Talde Private Equity and Naturex España S.A. Today, the company is 90% ADM and 10% CSIC. The founder (Dr. Ramón) had worked at CSIC for 23 years. He was Professor at the Institute of Agrochemistry and Food Technology of CSIC and coordinator of the Food Science and Technology CSIC area. "We were very good at publishing and participating in European projects, but we had a very low score of technology transfer to the sector", says Daniel. A new paradigm was needed, where scientists had contact with industry. With that purpose, CSIC boosted the foundation of Biopolis.

BUSINESS MODEL

In 2003, Biopolis board of directors did a study of the Spanish biotechnology industry, concluding that a lot of Biotech companies were sustained fundamentally by autonomic public funds. According to Daniel, they forbade the founders to seek for public funds and gave them €56.000, with the condition that in two years they must earn profits. The founders visited food, chemical and Pharma companies, offering them their services. In 2 years, they made profits and in 5 years they had enough to create the Lifesequencing division. "Our philosophy is to always put the client first. This has not changed with ADM acquisition", says Daniel.

"Over time, Biopolis changed the message and adapted to the client."

In 2017, Archer Daniels Midland (ADM), one of the 5 large agri-food companies worldwide, acquired 90% of Biopolis shares.

KEY CHALLENGES & ACHIEVEMENTS

"Spain could have had a better environment for innovation."

Since the company was founded, 47 children of Biopolis employees have been born.

The biggest challenge for Biopolis was the business environment. "It is a shame, because Spain had the potential (business sector on one hand, and a public science of high quality on the other). Nevertheless, political leaders were not able to create a good environment for innovation", says Daniel. He thinks that the biggest success of Biopolis are the children of Biopolis employees. For him, being able to settle down and establish a family during their time working at Biopolis means that workers believe in the company, which is an essential part of success.

GROWTH AND FUNDING STRATEGY

Daniel explains that it was not easy to find the first clients. They rented a car and visited several companies with the following offer: "Hello, we know how to do R&D, can we help you?". Most of the companies refused to give them a chance to prove themselves. However, things changed when they arrived at Ordesa, an infant nutrition company of Barcelona, and met with Montse Rivero (who was at that time, the scientific director). "She trusted in us. I have asked her many times why and she always says that she saw such curiosity and passion in us, that she was touched by us", says Daniel. Since then, more clients arrived, and in 2 years Biopolis was achieving profits.

"In the 1st meeting of the board of directors, they made it clear that we did not have to look for financing, but for clients."

FUTURE OF BIOTECHNOLOGY

"We should better define in what areas of biotechnology we can be competitive."

According to Daniel, agri-food biotechnology should be very relevant, especially if we want to enter the circular economy. He thinks Spain has a powerful food industry and very good public research groups working in both, agri-food and environmental biotechnology.

SOME ADVICE FOR FUTURE ENTREPRENEURS

- **"Identify your client type and once you have, dedicate yourself completely to them."**
- **"If the client is not satisfied, you don't have anything."**
- **"Don't be in 2 positions (public and private) at the same time, because you will fail in both."**

GRIFOLS, Continuous Innovation to Enhance Quality of Life

JOSE TERENCIO
VP Innovation & R+D Coordinator at Grifols
www.grifols.com

COMPANY TYPE
Healthcare company

TECHNOLOGY
Production of plasma-derived medicines, in-vitro diagnostics solutions and Pharmatec and intravenous solutions, among others.

FOUNDERS
José Antonio Grifols Roig and his sons José Antonio and Víctor Grifols

FOUNDED
November 1940, Sant Cugat del Vallès (Barcelona)

REVENUES
€4,318 M (in 2017)

R+D INVESTMENT
€311 M (in 2017)

COMPANY HISTORY

1940 Grifols Laboratories foundation by Dr. Grifols Roig

1943 Lyophilization process was patented

1945 Opening of Spain's 1st private blood bank (*Hemobanco*)

1951 Dr. Grifols Lucas develops the plasmapheresis technique

1958 First plasma fractionation plant in Spain begins operations

1973 Opening of a new production facility in Spain

1982 Alpha Therapeutic Corporation joins Grifols as a new shareholder

1987 Company reorganization; conversion to a Holding company

1990s Start of company's internationalization. 2 FDA's licences (manufacturing plant and product -albumin-)

2002 Grifols purchases the U.S. company SeraCare and its 43 plasmapheresis centres

2006 The company is listed on the Spanish stock market. The stock became part of the IBEX 35 index in January 2008

2011 Grifols acquires Talecris Biotherapeutics to become the third-largest global manufacturer of plasma-derived protein therapies

2014 and 2017 Diversification of company's activity through the acquisition of companies from the diagnosis sector. On-going expansion of plasma collection centres to become the global leader

TECHNOLOGY

Grifols is a global company specialized in the research, development, production and marketing of pharmaceutical and healthcare products. The company has 4 divisions. The most important (according to business volume) is **Bioscience**, which produces plasma derivates for the treatment of rare and chronic diseases. Followed by the **Diagnostics** division that is focused on the development and manufacture of diagnostic equipment and reagents for its use in clinical laboratories and blood banks. The **Hospital** division develops and manufactures intravenous pharmaceuticals, medical devices and logistic solutions for the hospital pharmacy. Finally, **Biosupplies**, which is dedicated to biological reagents for non-human use.

Grifols produces plasma-derived medicines for the treatment of rare and chronic diseases for patients in more than 90 countries worldwide.

BUSINESS MODEL

"Grifols' vertically integrated business model relies on the coverage of the entire value chain of its products."

The business model of Grifols is based on covering the entire value chain of its products, from development and manufacturing to marketing. Always with the objective of meeting the patient's needs in the therapeutic areas, in which the company has expertise. Moreover, Grifols invests in research and development projects based in-house and at their investee companies.

KEY CHALLENGES & ACHIEVEMENTS

In José's opinion, the major achievement of Grifols was the process of growth and internationalization in the Plasma Fractionation Industry, which is a highly regulated sector with high standards of quality. "Working in such a highly regulated and complex sector was also the major challenge".

Grifols has a global presence, with subsidiaries in 30 countries, 18.300 employees and with sales in more than 100 countries.

FUTURE OF BIOTECHNOLOGY

"There is an opportunity to obtain more specific drugs, which will result in greater safety and efficacy".

Biological medicines sector has experienced a very important growth in the last decade. "There is a unique opportunity to converge recent advances (new knowledge of the molecular bases of diseases, biological medicines production technologies, genetic manipulation tools, big data and nanotechnology) to produce more specific drugs", affirms José.

SOME ADVICE FOR FUTURE ENTREPRENEURS

- **"Be realistic and honest about your idea. An idea should be focused on solving a real and specific clinical problem, instead of trying to find some problem able to be solved with it."**
- **"At each stage of the project development, it is also very important to involve people with previous experience."**

MedLumics secured 34.4 Million Euros in Series B Funding in March 2017

COMPANY TYPE
Medical device start-up

TECHNOLOGY
Photonic technology for diagnostic imaging.

FOUNDERS
Eduardo Margallo and Jose Luis Rubio

www.medlumics.com

FOUNDED
2009 (operations started in 2011), Madrid

RAISED
€37.9 M

INVESTORS
Andera Partners, Seroba Life Sciences, Innogest, YSIOS Capital, Caixa Capital Risc, Edmond de Rothschild Investment Partners

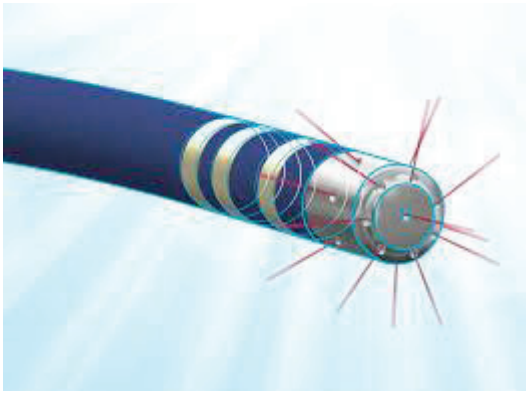
TECHNOLOGY

Atrial Fibrillation (AF) is the most common type of heart arrhythmia. An estimated 33.5 million people worldwide suffered from AF in 2010 and prevalence of the disease is expected to increase. **Radiofrequency (RF) ablation catheters** are becoming a first line therapeutic option for many arrhythmia patients. However, current systems do not allow accurate monitoring and control of lesion creation at the tip of the electrode. In the case of Atrial Fibrillation, imperfectly performed ablation has been linked to short and long-term recurrence. Moreover, inadequate energy delivery can produce pops and compromise patient safety.

MedLumics is developing **AblaView**, an optically guided RF catheter for the treatment of Atrial fibrillation (AF) and other arrhythmias. Using an optical analogue of ultrasound, it is able to determine catheter-wall distance and contact quality. This information, displayed during the navigation and ablation phases, allows creation of continuous lesions with controlled thickness. This is crucial to prevent pulmonary vein reconnection, and recurrence, after initially successful procedures. The company is currently completing development of a clinical version of the catheter with 360-degree, real time "view" of the tissue around the catheter tip.

MedLumics is a medical device start-up company that designs and manufactures integrated photonic devices using optical coherence tomography technology (OCT), a non-invasive light-based diagnostic technique that provides sectional information about tissue with high resolution.

AblaView will provide the clinicians with direct, real-time information on lesion formation in the tissue surrounding the catheter's radiofrequency electrode during the ablation process.



AblaView: Radio frequency Catheter with Optical Guidance for the treatment of Atrial Fibrillation (AF) and other Arrhythmias.

COMPANY HISTORY

MedLumics raised €34.4 million in Series B Funding in 2017. This financing was the largest in the history of Medtech in Spain and one of the largest in Europe that year.

The company was founded in 2009 with the goal of translating the latest technological and scientific developments in the biophotonics field into innovative and quality products for improving quality of life. It is based in Tres Cantos, Madrid. In 2011, MedLumics announced the closing of €3.5 million ($4.7 million) in Series A Funding, led jointly by YSIOS Capital and Caixa Capital Risc. The funds were used to complete the development of the company's imaging diagnostic platform and the recruitment of its executive and technical teams. DermaLumics was born as a spin-off from MedLumics in 2015. It is a global medical device company based in Madrid aimed to transform skincare through innovative imaging solutions based on Optical Coherence Tomography. DermaLumics developed NITID, a handheld diagnostic device designed to help dermatologists quickly and minimally invasively diagnose skin cancer. In 2015 it received the CE mark. In 2017, MedLumics raised €34.4 million in Series B Funding led by Edmond de Rothschild Investment Partners, to help advance the product and clinical development of the company's AblaView catheter.

MINORYX THERAPEUTICS has initiated a Pivotal Phase 2/3 Clinical Trial of MIN-102 for the Treatment of AMN

MARC MARTINELL
Chief Executive Officer
mmartinell@minoryx.com
www.minoryx.com

COMPANY TYPE
Drug discovery

TECHNOLOGY
New therapies for X-linked adrenoleukodystrophy and other Orphan CNS diseases

FOUNDERS
Joan Aymamí, Marc Martinell, Xavier Barril

FOUNDED
October 2011, Mataró (Barcelona)

RAISED
€22,5 M

INVESTORS
YSIOS Capital, HealthEquity, Kurma Partners, Chiesi Ventures, Roche Venture Fund, Caixa Capital Risc, Idinvest Partners and Sanfilippo Foundation

TECHNOLOGY

The company's leading program, a differentiated PPAR gamma agonist (MIN-102), is a candidate for X-linked Adrenoleukodystrophy (X-ALD), a genetic disease characterized by progressive neurological deterioration with no available pharmacological treatment. MIN-102 has the potential to treat both cerebral ALD (cALD) and adrenomyeloneuropathy (AMN), the two main forms of X-ALD. The drug candidate has successfully completed phase 1 clinical trials and is now in a pivotal phase 2/3 trial in adult AMN patients (in Europe and in the United States). Minoryx Therapeutics is also working on expanding the use of MIN-102 into the paediatric version of the disease and into other Central Nervous System diseases.

A phase 2/3 clinical study of MIN-102 has been initiated in adult patients with AMN.

COMPANY HISTORY

MIN-102 was granted Orphan Drug Designation by the European Medicines Agency (EMA) in 2016 and by FDA in 2017

In 2018, Minoryx Therapeutics spins off SEE-Tx platform into a new company, Gain Therapeutics.

Minoryx Therapeutics is a clinical stage biotech company that was founded in 2011 at the Mataró-Maresme TecnoCampus Park, with the mission of finding new treatments for rare diseases, mainly for the metabolic pathologies of genetic origin that affect children. In 2013, Minoryx signed an in-licensing agreement with IDIBELL for the use of a patent for the treatment of X-ALD. In 2015, the company completed a Series A funding of 19.4 million euros, led by YSIOS Capital, for the clinical validation of their lead drug candidate. Phase 1 clinical trial for MIN-102 was completed in 2017 and in 2018, phase 2/3 was initiated. In February 2018, Minoryx spun off Minoryx Site-directed Enzyme Enhancement Therapy (SEE-Tx) platform into a new company.

BUSINESS MODEL

According to Marc, the business model of the company is to develop their drugs and move them forward until they can. At some point, the company should be listed or be acquired by a bigger company.

Drug development and company acquisition.

KEY CHALLENGES & ACHIEVEMENTS

"Starting the phase 2/3 clinical study of MIN-102 in patients with adrenomyelo-neuropathy (AMN) has been a great achievement."

Marc considers that the success will be achieved when the product finally reaches the market. He considers all milestones as intermediate successes to achieve the real success. Nevertheless, "starting the largest ever pivotal study for X-ALD and being the most advanced company worldwide for this indication (in adult patients) is already a success, as we could be first to market", he says. Another important milestone was to close a round of almost 20 million euros in 2015. At that moment, it was the biggest round in the Catalan Biotech sector and the 3rd biggest in Spain. The CEO explains that a Biotech company has new challenges every day and that for Mynorix the major difficulty was to find investment during the initial steps of the company.

GROWTH AND FUNDING STRATEGY

Minoryx Therapeutics started with the founders' savings and with the money from people close to them. Rapidly, they raised funds from CaixaCapitalMicro SCR and ENISA. One year later, they were awarded with an INNPACTO grant (MINECO) and raised some funding from ACCIO. In 2013, Caixa Capital Risc (CCR) and Inveready made an investment of €1.5 M. In 2015, HealthEquity and CCR invested €1.6 M. 6 months later, the company completed Series A funding of €19.4 M. The round was led by YSIOS Capital and supported by Kurma Partners, Roche Venture Fund, Idinvest Partners and Chiesi Ventures.

"Fundraising was always difficult, regardless of quantity. At the beginning, our major support were public funds. Now, almost 90% of the company funds come from Venture Capital."

FUTURE OF BIOTECHNOLOGY

"Biotechnology should focus on non-covered medical needs."

According to Marc, medical needs are diseases that are really serious and that have a strong impact on patients, families and the Health System. "We could talk about technologies, but I think that new technologies are constantly being discovered and maybe the promising ones have not even been invented yet."

SOME ADVICE FOR FUTURE ENTREPRENEURS

- **"Talk to a lot of people from different sectors. Don't be afraid; without saying anything too confidential, you can learn a lot and obtain a very useful opinion."**
- **"Be realistic and always seek to maintain credibility. Don't commit yourself to do things that you already know you can't achieve. Investors will crosscheck everything you say and do."**

Mosaic Biomedicals Joins Forces with Northern Biologics to Accelerate the Clinical Development of MSC-1

JUDIT ANIDO
General Manager
janido@mosaicbiomedicals.com
www.mosaicbiomedicals.com

COMPANY TYPE
Drug development company

TECHNOLOGY
Personalized cancer treatments with a dual mechanism of action: eliminate CSCs and reactivate the tumour's immune system

FOUNDERS
Judit Anido, Joan Seoane, Josep Baselga

FOUNDED
April 2013, Barcelona

RAISED
Undisclosed

INVESTORS
Versant Ventures, Caixa Capital Risc, Business Angels

TECHNOLOGY

Mosaic's lead compound, MSC-1, is a *First-in-class* antibody that targets the Leukaemia Inhibitory Factor (LIF). LIF is an exciting emerging target in the immune-oncology area. LIF is hypothesized to contribute to tumor growth and progression by acting on multiple aspects of cancer biology, including immunosuppression within the tumor microenvironment (TME), and regulation of cancer initiating cells (CICs), which are thought to underpin tumor growth, metastasis and resistance to therapy. In 2018, MSC-1 began the First Human clinical trial in several tumor types in US, Canada and Europe.

Mosaic Biomedicals developed a first-in-class antibody against LIF, a cytokine overexpressed in certain solid tumours (lung, glioblastoma and pancreatic cancer among others).

COMPANY HISTORY

The technology was originated at the laboratory of Dr. Joan Seoane (director of the Translational Research Program at VHIO).

In 2016, Mosaic merged with Northern Biologics to enable the accelerated development of MSC-1 and conduct clinical trials. Celgene exercised an option to acquire certain rights to the MSC-1 program.

Joan Seoane first elucidated a role for the cytokine in cancer in a seminal 2009 publication in Cancer Cell in which Judit Anido is co-author. Afterwards, during Judit's MBA tenure in the US, during a meeting at the American Association of Cancer Research with Joan Seoane, it became clear that a biotech company was the best vehicle to rapidly translate the scientific discovery into a treatment to benefit patients and give back to the society. That was the starting point for Mosaic, a spin-off of the Vall d'Hebron Institute of Oncology, Catalan Institution for Research and Advanced Studies (ICREA) and the Vall d'Hebron Institute of Research (VHIR).

BUSINESS MODEL

The business model of Mosaic Biomedicals is not different from other Biotech drug development companies. They know that their greatest strength lies in the early stages of drug development (pre-clinical phase and Stages I and II of clinical trials), in which small companies are more flexible, quick and efficient in developing drugs than large Pharmas. "Small biotech companies like Mosaic are a good source of new and novel assets to grow the pipeline of big pharma companies", says Judit.

Mosaic Biomedicals plans to finish the early stage development of their drug portfolio and either license the drugs or sell the whole company to a Pharma giant.

KEY CHALLENGES & ACHIEVEMENTS

Mosaic Biomedicals' 1st financial round was led by Versant Ventures, a top 10 venture capital firm in the USA.

"Every day, Biotech companies have to overcome challenges"

According to Judit, Mosaic has been successful in surrounding themselves by the best partners. First financing round in 2014 was led by the US VC Versant Ventures and Caixa Capital Risc. In addition, Mosaic built an international team of experts in different development areas to help MSC-1 advance. In 2016, Mosaic merged with Norther Biologics, and partnered with Celgene through a build-to-buy deal. To run a biotech company, it is key to feel comfortable in an environment in constant evolution involving risk and uncertainty."

GROWTH AND FUNDING STRATEGY

Public funding received from the RETOS de Colaboración program, ENISA, CDTI, PROVA'T (CERCA) and ERC´s Proof of Concept (PoC), among others, have been essential in fuelling Mosaic's creation. Later on, private funding from Business Angels (personal friends of Joan Seoane and Judit Anido who believed in them and in the project), Versant Ventures and Caixa Capital Risc helped to consolidate and internationalize the company while accelerating the development of MSC-1. According to Judit, public funding is key to leverage private financing and de-risk the company at the initial stages.

"We always wanted investors that could bring not only the financial support but also the expertise and network. The best investors have brought companies to exit several times."

FUTURE OF BIOTECHNOLOGY

"I cannot imagine a future without research and biotech companies. There are still numerous unmet medical needs"

For Judit, scientific research is fundamental to understand the diseases and elucidate new treatments to tackle them. Biotech companies are the engines able to transform this research into solutions for patients.

SOME ADVICE FOR FUTURE ENTREPRENEURS

- **"First, understand what is the problem that you want to solve."**
- **"Then, build a very strong team around you that is able to execute the idea."**
- **"Running a biotech requires a special personality, you should feel comfortable dealing with risk and uncertainty and be a hard worker."**

ORYZON

ORYZON Started a Phase II Clinical Trial with ORY-2001 in Mild and Moderate Alzheimer's Disease Patients in May 2018

CARLOS BUESA
Chief Executive Officer
cbuesa@oryzon.com
www.oryzon.com

COMPANY TYPE
Biopharmaceutical company

TECHNOLOGY
Development of epigenetics-based therapeutics

FOUNDERS
Carlos Buesa, Tamara Maes

FOUNDED
2000, Cornellà de Llobregat (Barcelona). Headquarters in Madrid

REVENUE
€557.529 (1st semester 2018)

R&D INVESTMENT
€3.7 M (1st semester 2018)

TECHNOLOGY

Oryzon is a leader in the development of epigenetics-based therapeutics. Their therapeutic strategy is to treat the underlying causes of diseases such as cancer and neurodegenerative disorders, by targeting lysine specific demethylase 1 (LSD1), a histone modifying enzyme that removes methyl groups and regulates the expression of many genes implicated in disease progression. The company pipeline has 2 compounds: **ORY-1001 (IADADEMSTAT)**, in Phase I/IIA clinical trial for acute leukemia and small cell lung cancer; and **ORY-2001 (VAFIDEMSTAT)**, in Phase IIA for mild and moderate Alzheimer's Disease (AD), as well as Multiple Sclerosis (MS). The company is in negotiations with the FDA to obtain regulatory approval to perform a clinical study for AD in the US; and it has also initiated a regulatory dialogue to perform a new study to evaluate the potential of ORY-2001 for the treatment of psychiatric diseases.

Oryzon is a public clinical stage biopharmaceutical company, leader in the development of epigenetics-based therapeutics. They focus on oncology, neurodegenerative diseases and other unmet clinical needs.

COMPANY HISTORY

"At the end of 2018, the company will be conducting 5 clinical trials in Spain, France and the UK. We hope to start another one in the US at the beginning of 2019."

Oryzon was founded in 2000 by Carlos Buesa and Tamara Maes with the mission of using genomic and proteomic tools for the identification of biomarkers for serious diseases. In 2003, there was a substantial company growth thanks to Venture Capital investment and a mixed approach to service provision and internal R&D. In 2008, the company changed the strategy, and became a Biotech focused on the development of its own products and it acquired Crystax Pharmaceuticals in 2009. Oryzon is listed on the Spanish Stock Exchange since December 2015. During 2015-2016, the company raised €32 million, with additional €18.2 million raised from blue chip investors in the US and Europe in March 2017. Moreover, from 2014 to 2017 the company had a collaboration with Roche related to their lead oncology program and received more than $23 million. In 2018, Oryzon has almost 40 employees.

BUSINESS MODEL

Oryzon business model is to develop novel experimental drugs, typically until Phase I or Phase II clinical trials. Then, the company seeks to establish collaborations with pharmaceutical companies that can complete the drug development and its commercialization. In some special cases (orphan diseases), Oryzon may keep its option to fully develop its programs. The company collaborates with leading researchers and institutions from Europe and the US and develops common projects with other companies. In these collaborations they look for strategic component for program development or the opportunity to have access to an important technology.

Oryzon typically develops its investigational medicines till proof of concept and then partners the program with pharmaceutical companies able to get the approval from the drug agencies to bring these medicines to the patients.

KEY CHALLENGES & ACHIEVEMENTS

"The collaboration agreement between Roche and Oryzon, announced in 2014, gave Oryzon the necessary financial muscle, standing and endorsement to accelerate company's development."

"The major achievement of Oryzon was the agreement that we made with Roche in 2014. It was a transformation for us", says Carlos. The agreement was related with ORY-1001 molecule and its use for the treatment of acute myeloid leukaemia (AML). In the 24 months following the agreement, the company received $23 million. This collaboration represented for Oryzon visibility and international recognition, placing the company in a new dimension. "In July 2017, Roche made a strategic reorganization of its portfolio and returned the ORY-1001 molecule to Oryzon. This implied a change in our business strategy, as the resources that we had planned to allocate to our third molecule, ORY-3001 for the treatment of rare diseases, had to be allocated to re-boost ORY-1001", explains Carlos when he is asked about Oryzon's challenges.

FUTURE OF BIOTECHNOLOGY

According to Carlos, central nervous system diseases such as Alzheimer's and other dementias or psychiatric disorders such as Autism or Depression are like modern plague. Although there is a big challenge, the market interest has been reflected by small recent movements, like the listing of DENALI Therapeutics on NASDAQ or the increase in the value of BIOGEN's shares. In oncology, the combination of immunotherapy and epigenetics has also a promising future.

"Epigenetics is going to play an important role in neurological disorders and Oryzon is a leader in this field."

SOME ADVICE FOR FUTURE ENTREPRENEURS

- **"Starting your own business is an obstacle race, which entails risks and responsibilities."**
- **"First define your business type, understand the value chain structure and believe in the project. Then, start to build, starting from the 2 basic lines: science-team and funding."**
- **"Get rid of complexes. Spain has a first-class talent and every day is being more recognized outside our borders."**

Palo iofarma
Innovation through medicinal chemistry

PALOBIOFARMA Signed a Licensing Agreement to Develop Novel Adenosine-based Immuno-Oncology Treatments, in 2015

JULIO CASTRO-PALOMINO
Chief Executive Officer
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www.palobiofarma.com

COMPANY TYPE
Drug discovery

TECHNOLOGY
New medicines based on the modulation of the adenosine receptors

FOUNDERS
Julio Castro-Palomino Laria, Juan Camacho Gamez

FOUNDED
2006, Barcelona (Headquarters in Noáin, Navarra)

RAISED
€4 M

INVESTORS
Inveready, Fitalent and Sodena

TECHNOLOGY

The pipeline of Palobiofarma consists of 7 molecules:

PRODUCT	TARGET	INDICATION	DISCOVERY	PRECLINICAL DEVELOPMENT	PHASE I	PHASE II
PBF-680	Adenosine A1 Antagonist	Asthma /COPD				
PBF-509	Adenosine A2a Antagonist	Cancer				NOVARTIS
PBF-677	Adenosine A3 Antagonist	Ulcerative Colitis				
PBF-999	A2a/PDE-10 Inhibitor	Cancer				
PBF-1129	Adenosine A2b Antagonist	Pulmonary Fibrosis/Cancer				
PBF-1650	A1/A3 Antagonist	Psoriasis/NASH				
PBF-2828	CD73/CD39 Inhibitors	Cancer				

Palobiofarma is a company focused on the discovery of new drugs based on the modulation of adenosine receptors.

COMPANY HISTORY

Julio Castro always had the desire to start his own business. Nevertheless, he didn't do it until he had gained enough experience in the pharmaceutical industry. He believes that this experience has been essential for Palobiofarma's medium-term success.

The company was founded in 2006 in Barcelona, by Julio Castro-Palomino and Juan Camacho, who had more than 15 years of experience in drug discovery in several pharmaceutical companies. In 2011, the headquarters were moved to Pamplona. According to Julio, the founders' experience, their understanding of the needs, the challenges and the potential of the pharmaceutical business were keys for the success of Palobiofarma. Currently, the company has a team of 16 researchers, most of them with a PhD in science.

BUSINESS MODEL

Julio highlights 3 points about Palobiofarma's business model:

- **The company works with a semi-virtual business model.**
  They oversee the activities related to Intellectual Property (the design, synthesis and initial pharmacological evaluation of new compounds). The remaining activities (toxicology, regulatory, clinical trials and so on) are carried out by external collaborators.
- Once the drugs arrive to the earliest stages of the clinical development, Palobiofarma **licenses them to pharmaceutical companies**.
- The company is working towards the goal of making Palobiofarma as attractive as possible so that it can be **acquired by a multinational pharmaceutical company in two years**.

KEY CHALLENGES & ACHIEVEMENTS

Palobiofarma's major success was to sign its first license agreement with Novartis.

According to Julio, the signing of the first license agreement with the multinational pharmaceutical company Novartis in 2015 is without doubt, Palobiofarma's greatest success so far. With this agreement, Novartis acquired exclusive global rights to develop, manufacture and commercialize Palobiofarma's PBF -509. The agreement included an up-front of $15 million, with the possibility of increasing to $450 million if all milestones are achieved. Their major challenge was always to find investment. Julio says: "the road has been long and surviving the profound economic crisis of the years 2011 to 2014 was really difficult."

GROWTH AND FUNDING STRATEGY

Julio explains that Palobiofarma has been a successful company also thanks to public funding. Some grants that they have been awarded are: ENISA - MINECO, PID project-CDTI, INNPACTO and RETOS-MINECO, as well as some other European Projects. "Without this support it would have been impossible to take 6 projects into clinical trials", he says. Private investment has also been very important for the company. Palobiofarma raised a total of €4.5 million in three different financing rounds.

"Without public funding, Palobiofarma couldn't have taken 6 projects into clinical trials."

FUTURE OF BIOTECHNOLOGY

"New innovative drugs to "CURE" disease are needed."

Julio considers that despite last year's scientific advances, there is still a big unmet medical need. "It can be seen through the number of patients suffering from diseases such as cancer and Alzheimer's that still don't have an effective treatment".

SOME ADVICE FOR FUTURE ENTREPRENEUR

- **"Drug discovery and development can't be learned at university or business school."**
- **"If you want to start a drug discovery business, find someone that has experience in drug discovery in a pharmaceutical company."**

PEPTOMYC S.L. secured €4.2 M in Series A Funding, in 2017

LAURA SOUCEK
Chief Executive Officer
lsoucek@vhio.net
ww.peptomyc.com

COMPANY TYPE
Drug discovery and development

TECHNOLOGY
Cell penetrating peptides (CPPs) targeting the Myc oncoprotein for cancer treatment

FOUNDERS
Laura Soucek, Marie-Eve Beaulieu, VHIO and ICREA

FOUNDED
December 2014, Barcelona

RAISED
€5.2 M

INVESTORS
Alta Life Sciences, HealthEquity and Business Angels

TECHNOLOGY

Peptomyc is developing more effective and less toxic therapies for cancer patients. Their target (Myc) is a protein that enables cancer cells to grow and acquire treatment resistance. The aim of Peptomyc is to develop a first-in-class Myc inhibitor. In Laura's opinion, any pharmaceutical company would like to add such an inhibitor to its portfolio, as it would be the first in the market. Myc has the peculiarity of being an essential protein for tumoral cells, but not for normal cells. This therapy is the opposite of a personalized medicine, as it could be used for all cancer types. For practical reasons, they have begun with lung, breast and brain cancer.

Peptomyc is developing a new generation of cell penetrating peptides (CPPs) that inhibit Myc protein, for cancer treatment.

"For the first time, cancer cells could be attacked without damaging normal cells."

COMPANY HISTORY

"The decision of being an entrepreneur was a necessity at the beginning, in order to translate my research to the patients. Nevertheless, with time it has become a challenge that I face with a lot of excitement."

Peptomyc is a spin-off company of the Vall d'Hebron Institute of Oncology (VHIO) and the Catalan Institution for Research and Advanced Studies (ICREA). In an interview with Josep Tabernero and Andrés De Kelety (Director and Managing Director of VHIO), they explained what are the key aspects for VHIO's technology transfer success: 1)Technology transfer is a strategic element for the institution. Not only because it enables the translation of research findings to clinical practice, but also as a funding source. 2)VHIO is constantly in touch with leading Pharma. If the technology is of interest for them and there is a researcher with an entrepreneurial spirit, a spin-off is founded. It will have a First Option, but the patent will not be licensed to the spin-off, until a Venture Capital with enough money to take the company to Phase 2 clinical trials, invests in it. When the 1st investor enters the company, VHIO must recover the invested funds in the patent.

BUSINESS MODEL

The pipeline of Peptomyc is now in the pre-clinical phase. Its business model consists of product development from a Proof of Concept Stage into a successful Phase I/II product and then licensing it to a pharmaceutical company, which will be in charge of the commercialization. Peptomyc is currently looking for investors in order to fund the clinical development of Omomyc.

Development of the technology into a successful Phase I/II product and then licencing it to a Big Pharma.

KEY CHALLENGES & ACHIEVEMENTS

For Dr. Soucek, having her own company is a success. She feels proud of the public funding they have raised and of Peptomyc investors.

"Her major challenge was to learn how to explain the project from a business point of view."

According to Laura, researchers have a scientific background, so when they have to start a business, they don't feel comfortable because it's a step outside of their comfort zone. She feels proud of the following milestones: having raised more than €2 million of public funding, having strong investors like Alta Life Sciences and HealthEquity and having the support of Business Angels (which have followed the company in the 2 funding rounds). "The first steps of the company were really difficult and having a consultancy like GENESIS Biomed was very helpful, as they gave Peptomyc support in the business plan preparation and in the search for investors."

GROWTH AND FUNDING STRATEGY

Peptomyc is the result of 20 years of Dr. Soucek's research. The company has been able to grow thanks to public and private investment. National public grants have enabled them to take major steps, but they have also had funding from H2020. "This is a confirmation that what we do is of interest at both national and international level", says Laura. Private investment is really important for them, as more capital can be raised, and the company can gain acknowledgment of experts in the sector. In 2016, Peptomyc completed a Seed Funding of €1 million, led by HealthEquity, to reach preclinical validation for their lead candidate (Omomyc) in glioblastoma. In 2017, the company secured €4.2 million in series A funding, led by ALTA Life

"Every time you receive private investment, you have to share the company management with other people. I am really happy with the investors we found, because we are absolutely aligned."

FUTURE OF BIOTECHNOLOGY

"The health sector will undergo an exponential growth in the coming years."

Laura thinks that the health sector is the one that has major potential in the future. "In oncology, and also in other diseases, we are seeing a focus on patient's needs and complete changes in treatment protocols."

SOME ADVICE FOR FUTURE ENTREPRENEUR

- **"The strength of a company is its team. Choose your team in an intelligent way."**
- **"Recognizing your own limits is the first point to complement your forces with other's forces."**
- **"Find people with different experience, knowledge and points of view."**

PHARMAMAR, a World Leader in the Development and Commercialization of Anticancer Drugs of Marine Origin

CARMEN EIBE
Project Coordination Director
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www.pharmamar.com

COMPANY TYPE
Biopharmaceutical company

TECHNOLOGY
Development and commercialization of anticancer drugs of marine origin

FOUNDER
José María Fernández Sousa-Faro

FOUNDED
1986, Colmenar Viejo (Madrid)

TURNOVER
€179,4 M

R&D Expenditure
€78.5 M

TECHNOLOGY

PHARMAMAR is a pioneer in the development of antitumor drugs of marine origin, exploiting marine biodiversity as an unexplored source of new active principles. The first product of their oncology pipeline is **Yondelis®.** It is used for the treatment of different types of cancer (such as soft tissue sarcoma or ovarian cancer). **Zepsyre®** (lurbinectedin) is being developed for the treatment of small cell lung cancer, pancreatic cancer and Ewing sarcoma. **PM184** is being studied for colorectal cancer and solid tumours. **PM14** is currently undergoing a Phase I clinical trial for solid tumours. **SYLENTIS** and **GENOMICA** are within the PharmaMar Group**.** The former has an active R&D program aimed at the identification of novel compounds for the treatment of eye diseases and the latter has several projects in the design, development and automation of in vitro diagnostic systems.

Yondelis® was approved for commercializa -tion in 80 countries and in the main oncology markets: the US, Europe and Japan.

COMPANY HISTORY

PharmaMar, S.A. is the holding company of a group of companies (Pharma Mar Group) which operates in biopharmaceuticals and consumer chemicals: Genomica, Sylentis, Zelnova and Xylazel.

PharmaMar was founded in 1986 by its current president, José María Fernández Sousa-Faro and became the parent company of the Pharma Mar Group in 2015, through a reverse merger of Zeltia (absorbed company) into PharmaMar (acquiring company). Genomica (founded in 1991) entailed the entry of the group in the genetic and molecular diagnosis market. Sylentis (2006) aims at covering medical needs using gene silencing techniques (RNAi) for the development of innovative drugs. Zelnova (1991) is focused on the development and marketing of cleaning products for households and restaurant's industry. Xylazel (1939) produces and commercializes paint and varnishes.

BUSINESS MODEL

The PharmaMar Group generates its revenues from two main areas: biopharmaceuticals and consumer chemicals, the former being its main line of business. Specifically, the Group's primary activity is to carry out all necessary activities to launch anti-tumour drugs of marine origin to the market: from basic research to approval and marketing, through its preclinical and clinical development, production and conditioning and logistics distribution. The Group's strategy also includes the search for strategic alliances with partners, preferably industrial, that will invest and collaborate in advancing the compounds through the various research phases and in subsequent marketing. PharmaMar's network not only enables it to sell its products directly in the EU, but also provides scope to leverage future opportunities to sell third-party products.

Since the beginning, PharmaMar has maintained an integrated business model: from basic research to approval and marketing. The model includes having its own sales network covering Europe.

KEY CHALLENGES & ACHIEVEMENTS

"In 2003, the European Medicines Agency rejected Yondelis®. Today it is the most widely used second-line treatment for soft tissue sarcoma"

In 2007, PharmaMar became the first Spanish company to receive authorization from the European Commission for the commercialization of an anti-tumour drug for soft tissue sarcoma (Yondelis®) and in 2009, for ovarian cancer. Later, the drug was also approved in the US and Japan, which was a great achievement for the Spanish Biotechnology Industry. "With 20 years of experience, PharmaMar has gone through very difficult times, including those when Biotechnology was unheard of in Spain", says Carmen. In 2003, the European Medicines Agency rejected Yondelis®. Nevertheless, in 2007 it was approved and according to Carmen, today it is the most widely used second-line compound in Europe for the treatment of soft tissue sarcoma, with a market share of around 31%.

FUTURE OF BIOTECHNOLOGY

"Genomic editing technologies like CRISPR and big data open a new opportunity for a faster discovery of more effective treatments."

Carmen affirms that medicine has evolved spectacularly in the last 20 years. Even so, there are unsatisfied medical needs. "Approaches can differ (immunotherapy, small interference RNA or chemical molecules), but all of them should focus on new solutions for patient's needs."

SOME ADVICE FOR FUTURE ENTREPRENEUR

- **"Keep going and keep an open mind! A biotech project is a long-distance race and during this travel you will need to be open to innovation and potential collaborations in a fast-paced environment."**

PLANTRESPONSE
STRONGER BY NATURE

PLANTRESPONSE closed a €5.7 M Series A Financing in 2015

EDUARDO QUEMADA
General Manager
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COMPANY TYPE
Agricultural biotechnology company

TECHNOLOGY
Development of innovative products to improve crops health and growth.

FOUNDERS
Antonio Molina Fernández and Pablo Rodríguez Palenzuela

FOUNDED
March 2008, Pozuelo de Alarcón (Madrid)

RAISED
€5.7 M

INVESTORS
Monsanto Growth Ventures, Middleland Capital, Caixa Capital Risc and Novozymes

TECHNOLOGY

PlantResponse is a Plant Biotech focused in the development of a sustainable agriculture by developing products in 3 different areas:

- **Plant Health Care**: identification of the pathogen molecules that are detected by plants as a warning signal. Application of these molecules to crops for the activation of their natural defence mechanisms.
- **Plant stress**: identification of the compounds that plants produce to overcome adverse conditions. Test if exogenously applied compounds can modulate the adaptation of the plant to stress.
- **Nutrient use efficiency:** identification of microorganism that interact with plants by enhancing the absorption of limiting nutrients in order to reduce the use of fertilizers.

PlantResponse has an exclusive Fast-Track platform that turns discoveries into products, which are solutions for a wide range of crops that improve plant health and promote yield.

COMPANY HISTORY

In October 2017 PlantResponse opened the new North American headquarters in North Carolina, a key location for the North American market.

In 2007 Pablo Rodríguez and Antonio Molina, two teachers from the *Universidad Politécnica de Madrid (UPM)*, presented a new business idea in the *ActúaUPM* contest for innovative ideas based on Antonio's research in the natural defences of the plants. The project was awarded second prize and in February 2008, PlantResponse was founded as a UPM spin-off. Due to the 2008 financial crisis, the company could not start its activity until 2011, thanks to the Neotec II Program (from the Centre for Industrial Technological Development, CDTI) and the incorporation of Camposeven. In November 2013, PRB1 was commercialized as Stemicol. In 2015, the company raised €5.7 million in Series A funding.

BUSINESS MODEL

The collaboration of PlantResponse with worldwide leader research groups, has allowed not only the publication of research discoveries, but also to turn these discoveries into commercial products. The company's products are marketed mainly in Western Europe, but now they are entering Eastern Europe and the United States.

PlantResponse Business model is to develop and commercialize novel products of natural origin that enhance crop performance, improve crop quality and promote yield potential.

KEY CHALLENGES & ACHIEVEMENTS

"PlantResponse major achievement was to attract the attention of international investors, which in my opinion means that the technological component and the development potential of our company is very high."

PlantResponse major challenge was getting funding. Eduardo explains that not only he launched the company during the financial crisis, but he also did it in Spain, where private funding was limited. He says: "in a global market, in which you are competing with other companies that have more funding or resources to access that funding, you are placed at a disadvantage". He thinks that an achievement of PlantResponse was the quick development of novel technologies and products that attracted the attention of international investors. "Another achievement has been the tight collaboration that the company has with leading international research groups."

GROWTH AND FUNDING STRATEGY

In 2011 PlantResponse obtained funds from Neotec II Project (CDTI) and started a partnership with Camposeven, a strategic partner with over 40 years' agricultural experience. Camposeven investment increased the company's capabilities to perform field trials and allowed them to get first-hand knowledge about the market and growers' needs. In 2015, they raised €5.7 million in Series A funding with the participation of Monsanto Growth Ventures, Middleland Capital, Caixa Capital Risc and Novozymes. This prompted the start of trials in more than 20 countries.

"The collaboration with leading national and international researchers in the company's sector has been key for PlantResponse development."

FUTURE OF BIOTECHNOLOGY

"New and more sustainable technologies can be developed if we have more knowledge about Plant defence and adaptation mechanisms."

In the plant biotechnology sector, the future is genetic engineering with the CRISPR-Cas9 technique, the study of the plant microbiome and the study of plant physiology.

SOME ADVICE FOR FUTURE ENTREPRENEURS

- **"Conduct a market study to demonstrate that there is an unmet need."**
- **"Choose good partners, with whom you are aligned."**
- **"Own a powerful technology or collaborate with people that have it."**
- **"Define your business model and focus on the areas, in which you can be the best."**

Progenika Biopharma

GRIFOLS

95% of the Shares of PROGENIKA BIOPHARMA were Acquired by the Pharmaceutical Company Grifols

ANTONIO MARTÍNEZ
Chief Executive Officer
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www.progenika.com

COMPANY TYPE
Molecular Diagnostics

TECHNOLOGY
Design, development and production of new diagnostic tests

FOUNDERS
Antonio Martínez, Laureano Simón and Corina Junquera

FOUNDED
2000, Derio (Bizkaia)

RAISED
€11,5 M

INVESTORS
Grifols 95%
Others 5%

TECHNOLOGY

Progenika works in 4 different areas:

- **Immunohematology**: they have developed a kit (BLOODchip) to identify rare blood types (those that are different than the common ABO and Rh-). The test ensures maximum compatibility between donor and patient in transfusion therapy.
- **Cardiovascular**: a genetic test for the diagnostic of Familial Hypercholesterolemia.
- **Pulmonary**: A1AT Genotyping Test, for a genetic diagnosis of alpha 1 antitrypsin deficiency.
- **Autoimmunity**: PROMONITOR, a test designed for monitoring the clinical response of patients undergoing biological therapy.

The company designs, develops and manufactures diagnostic methods for the detection of biomarkers associated to human diseases.

COMPANY HISTORY

When the company was founded, they didn't have any technology. They elaborated a business plan to see which products could be developed and stablished strong collaborations with universities and research centres.

Progenika Biopharma SA is a biotech company founded in 2000 with headquarters in Derio, Bizkaia (SPAIN). The founders were classmates in a master's degree at the University of Navarra. After doing their PhD and career in science, they decided to start they own project. Company's first product, a test to genetically diagnose Familial Hypercholesterolemia, was a collaboration with the University of Zaragoza. The second product (a blood genotyping test for the identification of blood group variants) was developed in the framework of a European consortium, which involved the leading European blood banks. Nowadays, the company has a Staff of more than 70 highly academic and scientific qualified professionals and is a GRIFOLS company.

BUSINESS MODEL

Progenika's business model is the design, development and manufacture of new molecular diagnostic tests. Carrying out the worldwide commercialization is extremely complicated for a biotechnology company. Therefore, before becoming part of Grifols, they used to stablish distribution agreements to commercialize their products.

Nowadays, Grifols is in charge of the commercialization of the diagnostic tests developed by Progenika Biopharma.

KEY CHALLENGES & ACHIEVEMENTS

The company's major success was when in 2013, Grifols acquired 60% of its equity, for €37 M. By 2018, Grifols owns 95,23% of Progenika's capital.

The major challenge during the early stages of the company was the recruitment of qualified personnel. "For the initial phases of a start-up it is crucial to have a good team". Antonio considers that having selected an excellent team was also one of their keys to success. According to Antonio, "the success of the project has culminated with the acquisition of the company by the multinational Grifols. This has been a success for the company, the investors, the shareholders and the team".

GROWTH AND FUNDING STRATEGY

Progenika was funded through the typical phases of a start-up. The company had a pre-seed stage, where the founders and friends made their contribution. A seed stage with the support of business angels and seed capital from the *Diputación de Bizkaia*. A growth stage, when venture capital entered. And the exit stage, when the company was acquired by Grifols. Regarding public funding, Progenika did also receive funds from the Basque Gobernment, the Spanish Ministry of Science and Technology and the European Union. Antonio remarks that the Basque Country has an exceptional entrepreneurial environment and that there, entrepreneurs are acknowledged.

"The autonomous community of the Basque Country has a very favorable entrepreneurial environment."

FUTURE OF BIOTECHNOLOGY

"Diagnostic tools have to be simplified and automated. But also research should focus on an easy interpretation of the results."

Antonio considers that massive sequencing is an extremely powerful tool in the molecular diagnostics area. And in therapeutics, biological drugs have a promising future.

SOME ADVICE FOR FUTURE ENTREPRENEURS

- **"Don't rush. Before becoming an entrepreneur, you must train yourself both technically and from a business perspective."**

REIG JOFRE is 5th Spanish Pharmaceutical Company by Turnover listed on the Spanish Stock Exchange

ISABEL AMAT
Global Head of Innovation and Pipeline Management
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www.reigjofre.com

COMPANY TYPE
Pharmaceutical company

TECHNOLOGY
Research, development, manufacture and marketing of pharmaceutical products and nutritional supplements

FOUNDER
Ramón Reig Jofre

FOUNDED
1929, Sant Joan Despí (Barcelona)

SALES
€168 M (in 2017)

EXPANSION INVESTMENTS
€17 M (in 2017)

TECHNOLOGY

Reig Jofre is specialized in 3 different areas:

- **Pharmaceutical technologies:** development and manufacture of antibiotics and injectable products (distributed in more than 65 countries).
- **Specialty products:** research, development, manufacture and marketing of dermatology, respiratory, gynaecology and paediatrics products.
- **Healthcare: food supplements** marketed under Forté Pharma brand and ORL products

Reig Jofre is a pharmaceutical company with an extensive experience in R&D, regulatory, manufacturing, commercialization and licensing services.

COMPANY HISTORY

Reig Jofre has almost 1,000 employees, 4 development and manufacturing centres in Europe, direct sales in 7 countries and over 130 commercial partners in more than 65 countries worldwide.

Reig Jofre started as a small pharmacy in the neighbourhood of Gràcia, Barcelona. The company was founded by Ramón Reig Jofre in 1929. In 1970 there was a change in the head of the family business to Juan M. Biosca. The current CEO is Ignasi Biosca, grandson of the founder. During these years, the acquisition of different companies and their international growth has allowed them to become a reference company in Spain for its growth and innovation. Isabel remarks: “the family has always believed that innovation and development are important drivers for the growth of the company. Therefore, they have always reinvested their profits back into expansion and development.”

BUSINESS MODEL

Reig Jofre develops, manufactures and markets its own products. Moreover, the company collaborates with biotechnology companies and research groups from different countries, accompanying them (through formulation and freeze drying to stabilize complex products) until their products become optimal pharmaceuticals to reach the clinical trials and the market. This collaboration can be offered as a service. Although, in some cases Reig Jofre is fully involved in the project and decides to acquire participation in the company.

The business model of Reig Jofre is the development, manufacture and marketing of its own products.

KEY CHALLENGES & ACHIEVEMENTS

A recent achievement of Reig Jofre is the launch of Remikaf in Indonesia, in collaboration with Kimia Farma (announced in September 2018)

According to Isabel, Reig Jofre major challenge was to achieve the commercialization of one of its products (Remifentanil) in the Japanese market. "This market is extremely demanding, and the negotiations lasted for more than 4 years". They have now achieved the entry of this product in the Indonesian market. In her opinion, another important challenge that pharmaceutical companies face is to maintain the company's enough flexible to incorporate innovation. To develop and manufacture biotechnology, as well as to adapt to continuous regulatory changes and the changing market. "There are collaborations that we have with Biotech that allow us to incorporate innovation in a more agile way and accompany new projects towards regulatory compliance and industrial manufacturing", says Isabel.

GROWTH AND FUNDING STRATEGY

Reig Jofre's policy has always been internationalization and the reinvestment of their benefits into expansion, development and innovation to drive company's growth. During the last 50 years they have acquired different Spanish and international companies. At the end of 2014, they merged with Natraceutical S.A., owner of Forté Pharma Laboratories (a key player in food supplements), thus entering the area of health care. With this merge, the company was listed in the Spanish stock exchange, and became public and transparent.

"As Reig Jofré turnover grew, so did the reinvestment in the company."

FUTURE OF BIOTECHNOLOGY

"Biotechnology, medical and digital technology will be key to find better treatments and health solutions."

"Biotechnology will be crucial for diseases that still have unmet needs", says Isabel. She thinks that in the future we will not only talk about treatments, but also about health solutions. "Treatments will be accompanied by a service, monitoring a better control of the illness and a closer relationship between patients and doctors."

SOME ADVICE FOR FUTURE ENTREPRENEURS

- **"Have a good team of people with energy and tenacity that believe in the product and wish to fight for it."**
- **"Try to find the investors that can add value and accompany you with their experience."**

SANIFIT

Sanifit Successfully Completed the Phase II Clinical Trial of SNF472 in Patients with Calciphylaxis, in March 2018

JOAN PERELLÓ
Chief Executive Officer
joan.perello@sanifit.com
www.sanifit.com

COMPANY TYPE
Biopharmaceutical company

TECHNOLOGY
Development of treatments for calcification disorders

FOUNDER
Joan Perelló and Bernat Isern

FOUNDED
2007, Palma

RAISED
> €40 M

INVESTORS
Caixa Capital Risc, MGA Business Consulting, HealthEquity, YSIOS Capital, Lundbeckfonden, Forbion, Gilde HealthCare, Andera Partners, Baxter Ventures

TECHNOLOGY

Sanifit is a biopharmaceutical company that develops treatments for calcification disorders. **SNF472** is the company's lead compound and it is in development for the treatment of calciphylaxis and cardiovascular disease end-stage renal-disease (ESRD)-haemodialysis. Sanifit's SNF472 has a new mechanism of action, blocking the final common pathway of calcification independently of its origin without interfering directly with calcium and phosphate blood levels.

Sanifit is focused on the development of solutions for unmet needs in calcification disorders.

COMPANY HISTORY

Sanifit has started a SNF472 Phase 3 pivotal study for the treatment of calciphylaxis. The company is also investigating SNF472 in a Phase 2b study in CV-ESRD, with results expected in 2019.

In 2003, the cofounders of Sanifit (Bernat and Joan) presented their first business plan in an "Ideas Award" and they won the first price. The company started activities in 2007 as a spin-off of the University of the Balearic Islands. In 2012, the company's lead compound (SNF472) was granted orphan drug designation for the treatment of calciphylaxis from both the EMA and the FDA. In 2016, Sanifit expanded its activities in the USA with the incorporation of a subsidiary with offices in San Diego. In 2018, Sanifit has completed a phase II proof of concept trial in patients with calciphylaxis and the phase III study has started. The ongoing phase IIb study (CaLIPSO) in ESRD patients on dialysis is evaluating the effect of SNF472 on progression of arterial calcification, and it will be finished in 2019. The company has 25 professionals, half of them working in Palma (Spain) and the other half in California (USA).

BUSINESS MODEL

Sanifit's business model is based on the value generated from the data of its clinical programmes. As a private company, it is working on different options, which include a public offering change.

The company works to advance its clinical pipeline until registration.

KEY CHALLENGES & ACHIEVEMENTS

"During the economic crisis, we were on the edge of the abyss. We worked with tenacity to ensure that SNF472 could start clinical trials"

According to Joan, an achievement of Sanifit has been to bring together a great team of people, who for him are the main actors of the project's progress. The biggest challenge was to rebuild the company after it collapsed. "During the financial crisis, we underwent a severe corporate restructuring and were on the edge of the abyss. With perseverance, we managed to start clinical trials with SNF472 and ended up raising the biggest private funding round ever in the Spanish biotechnology sector", says Joan.

GROWTH AND FUNDING STRATEGY

Sanifit accomplished a series B capital increase of 3.6 million euros in an operation led by Caixa Capital Risc in 2014. The venture capital firm HealthEquity, the company Somtobir, and the Nefrona Foundation were also involved in this round. In 2015, Sanifit raised €36.6 million ($41.3 million) in a Series C financing round. The investment was led by YSIOS Capital and supported by a substantial syndicate of new investors including Lundbeckfond Ventures, Forbion Capital Partners, Gilde Healthcare, Edmond de Rothschild Investment Partners, Caixa Capital Risc and Baxter Ventures.

"In 2015, Sanifit raised €36.6 M ($41 M) in a series C round, which still is the biggest private founding round ever of the Spanish Biotechnology sector."

FUTURE OF BIOTECHNOLOGY

"RNA interference, CRISPR or drug delivery systems"

According to Joan, there is growing interest in rare diseases. Techniques like RNA interference, CRISPR or drug delivery systems are receiving a lot of attention.

SOME ADVICE FOR FUTURE ENTREPRENEURS

- **"Surround yourself with people that knows more than you in different areas."**
- **"During the journey, you will find yourself standing at a crossroads. These moments, in which you will have to make decisions, often with a variety of opinions in the team, are the most crucial for projects. Be cool and brave in the key moments."**
- **"You miss 100% of the shots you don't take. You won't succeed, if you don't try."**

STAT-DIAGNOSTICA was Acquired by QIAGEN in January 2018

COMPANY TYPE
Molecular diagnostics company

TECHNOLOGY
Innovative diagnostics, simple and fast syndromic testing

FOUNDERS
Jordi Carrera and Rafael Bru

www.stat-dx.com

FOUNDED
2010, Barcelona

RAISED
€44 M

INVESTORS
Gilde Healthcare, YSIOS Capital, Kurma Partners, Idinvest Partners, Boehringer Ingelheim Venture Fund, Caixa Capital Risc, Axis and Siemens Venture Capital

TECHNOLOGY

The QIAstat-Dx (DiagCORE Platform), developed by STAT-Diagnostica (STAT-Dx), is a Near Patient Testing system for rapid and precise molecular diagnostics and immunoassays. The platform is designed to enable scalable end-to-end or "sample to insight" processing of up to 48 molecular targets simultaneously, with the goal of diagnosing syndromes such as serious respiratory or gastrointestinal infections, as well as for use in oncology. QIAstat-Dx received CE-IVD marking in January 2018 and QIAGEN announced its launch in Europe in April 2018. QIAstat-Dx is now being launched with an upgraded CE-IVD-marked respiratory panel that detects 21 pathogens. The panel is the first test in a deep and broad pipeline of planned assays for QIAstat-Dx which spans infectious diseases, oncology, companion diagnostics and other disease areas.

STAT-Dx is an innovative molecular diagnostics company specialized in the development of advanced molecular diagnostic systems aimed at supporting Timely and Efficient Patient Care, while Optimizing Laboratory and Hospital Processes & Operations.

COMPANY HISTORY

In January 2018, QIAGEN agreed to acquire all shares of STAT-Dx for €118 M in cash and additional payments of up to €36 M based on the achievement of regulatory and commercial milestones.

STAT-Diagnostica, based in Barcelona, was founded by Jordi Carrera and Rafael Bru in 2010. The company closed a €2 million Series A round in 2011, led by YSIOS Capital. In 2013, they announced a closing of a Series B financing round totalling €17 million, led by Kurma Partners. In 2016, STAT-Dx raised €25 million in a Series C Financing led by Gilde Healthcare. As of April 27, 2018, STAT-Dx Life S.L. operates as a subsidiary of QIAGEN N.V.

TiGENIX
Living Medicines

TIGENIX was Acquired by TAKEDA, in July 2018

COMPANY TYPE
Biopharmaceutical company

TECHNOLOGY
Novel therapies, based on the anti-inflammatory properties of stem cells

KEY FOUNDING STAFF
Claudia D'Augusta and Eduardo Bravo

www.tigenix.com

FOUNDED
TiGenix (2000, Leuven-Belgium); Cellerix (2004, Madrid-Spain)

DEALED
€520 M with TAKEDA

PAST INVESTORS
Novartis Venture Fund, Roche Venture Fund, YSIOS Capital, Ventech, Life Science Partner, Genetrix and BioPharma Capital

TECHNOLOGY

TIGENIX is a biopharmaceutical company focused on exploiting the anti-inflammatory properties of stem cells to develop novel therapies for serious medical conditions. TiGenix has two proprietary platforms of expanded allogeneic stem cells: 1. Expanded adipose-derived stem cells (eASCs) and 2. Cardiac stem cells (CSCs). TiGenix has 3 drug candidates under development: **Alofisel® / Cx601 (darvadstrocel):** locally administered eASCs for the treatment of complex perianal fistulas in Crohn's disease patients. **Cx611:** Systemic administration of eASCs for the treatment of autoimmune diseases. **AlloCSC-01:** Intracoronary administration of CSCs for the treatment of acute ischemic heart disease.

Alofisel®: partnered with Takeda Pharmaceuticals.
Cx611: currently being evaluated in a Phase Ib/IIa trial in severe sepsis.
AlloCSC-01: 1 year data from CAREMI Phase I/II study demonstrated safety in acute myocardial Infarction (AMI)

COMPANY HISTORY

CELLERIX → Series A $7.6 M, Series B $27.2 M + $27 M, Series C $37.7 M → TiGenix acquisition $79.9 M → TAKEDA acquisition €520 M

In July 2018, TiGenix was acquired by Takeda. The acquisition has a value of €520 M

Cellerix was a spin-off company of Genetrix. The original idea for its lead product came from Dr. Damian Garcia Olmo (surgeon at Hospital Universitario La Paz, Madrid), specialist in the treatment of complex perianal fistulas in Crohn's Disease. In 2005, the company raised a Series A funding of $7.6M . Between 2007 and 2009 Cellerix raised a total of $54.2M in two equal tranches to close its series B round of funding. The round was led by YSIOS Capital Partners, Life Science Partners and Ventech. Genetrix also played a key role in the deal, and two of Cellerix' investors-Roche Venture Fund and Novartis Venture Fund- significantly increased their stake. In 2010, a Series C funding of $37.7M was raised and in 2011 TiGenix acquired 100% of Cellerix for $79.9M.

3P and Intervacc complete Manufacturing Agreement for New Vaccine Against Equine Strangles

Dámaso Molero
General Manager
damaso@3pbio.com
www.3pbio.com

COMPANY TYPE
Biopharmaceutical company

TECHNOLOGY
New Biological Entities (NBEs) and Biosimilars manufacturing

FOUNDERS
SODENA, Idifarma, Suan Farma and DRO

FOUNDED
2006, Noáin (Navarra)

REVENUES
€16 M (in 2017)

INVESTORS
Grupo Infarco

TECHNOLOGY

1. Biological products: 3P Biopharmaceuticals' (3P) main activity is the development and manufacture of recombinant proteins. The company offers the following services: genetic construct, cloning, clonal selection, small-scale process development, intermediate scaling and manufacture for preclinical research, additional scaling and GMP manufacturing for clinical studies, process validation and characterization, commercial manufacturing, development of the analytical package and its validation according to the projects' needs. Through 3P collaborating companies, they complete their offer with the phases "fill and finishing". **2. Cell Therapy:** 3P is the first Spanish CMO that offers full service to develop and manufacture processes and products of Advanced Therapy. Moreover, they have developed a cell bank of cardiac stem cells for myocardial infarction.

3P Biopharmaceuticals is a leading company in the development and manufacture of biological and cell therapy products.

COMPANY HISTORY

Nowadays, 3P is a Contract Development and Manufacturing Organization specialized in the process development and GMP manufacture of biopharmaceutical and cell therapy products, from early stages up to clinical and commercial.

The company was founded in 2006 as a result of the favourable evolution of CIMA (Centre for Applied Medical Research) - DIGNA project and as a business opportunity in Spain since there were no companies that could completely develop biologics, and neither manufacture them with Good Manufacturing Practices certification. Given the need to access the international market, the company was built to manufacture recombinant proteins and cell therapy products and it was Certified GMP by The Spanish Agency of Medicines and Medical Devices, in 2009. The company started its first Biosimilar project in 2012 and it signed its first multinational contract in 2013. In 2018, 3P has around 200 workers and an international focus. Dámaso remarks, "We have reached the break-even point, what is really relevant for a pure biotechnological company like 3P".

BUSINESS MODEL

Europe is the main market of the company. 3P has activity and clients in Norway, Sweden, United Kingdom, France, Belgium, Holland, Switzerland, Italy, Germany and Spain. They have also customers in the USA, Mexico, Australia, India and Hong Kong.

3P Biopharmaceuticals business model is to offer an integral service for "biological" drugs development, from drug discovery to market.

KEY CHALLENGES & ACHIEVEMENTS

3P major challenges were to understand the company's market, to find professionals with experience in the development of industrial processes and to overcome the economic crisis.

In Dámaso's opinion, the major success of 3P Biopharmaceuticals was to understand the market and the specific needs of each client, what enabled them to offer a full service that covers all the steps of the process development and build enough clients' trust. "The keys to success have been two concepts: work with the client (not for clients) and to be always there", says Dámaso. Another achievement was to integrate multiple technologies (that were available in the market) and personalize them for each specific client. Dámaso explains that the company had to overcome 3 challenges. The first one was to understand the company's market and become visible in a strongly demanding market. The second challenge was to build a professional team. As they couldn't find professionals in Spain with experience in industrial processes development, they had to search internationally. "Today, we are a multidisciplinary team of 15 nationalities", he says. Their third challenge was the economic crisis, which had a great impact in most of their clients, as well as in public R&D funds and investment.

FUTURE OF BIOTECHNOLOGY

Dámaso believes that new expression and purification processes that allow the development of complex molecules in a more efficient way, need to be investigated.

"Biotechnology should focus on the development of more efficient production systems to reduce development and manufacturing costs."

SOME ADVICE FOR FUTURE ENTREPRENEURS

- **"You should have the desire and the drive to create something valuable."**
- **"Let yourself be advised."**
- **"Have a backup plan."**

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ASEBIO the Spanish Bioindustry Association. It's mission is to bring together companies, associations, foundations, universities, research and technology centers that carry out activities directly or indirectly related to biotechnology in Spain.

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