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IPO listing of the only Italian company at Nasdaq: Genenta Science S.P.A. case

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INTRODUCTION

Many companies, in the course of their life cycle, decide to proceed with listing on one of the stock markets around the world. The IPO has always been a particularly important moment for businesses, a company can raise funds without resorting to debt, thus representing an additional form of financing by raising new capital. In particular, the companies operating in a complex and capital intensive sector like biotechnology require substantial funds and experience to be able to compete in the global market.

The purpose of this paper is to provide a knowledge base to describe and analyze main economic, financial and strategic reasons of the initial public offering on the NASDAQ Stock Exchange, taking as a case study the recent listing of Genenta Science S.P.A on December 20, 2021.

In particular, its ultimate goal is to understand whether the IPO is a strategy to be leveraged for innovation and development of the biotech market. Furthermore, a key objective of the entire paper is to understand how technological progress can influence the delicate healthcare environment in which we find ourselves, using innovative technology applied to medicine to revolutionize and cure important disease such as cancer. Lately, several signs showing an inevitable trend toward the medical sector (eg. Covid-19), have speeded up processes and given a boost to the technological development.
This paper is divided in three different chapters, each structured as follows:

1. Chapter I aims at explaining the nature and operation of the IPO transaction to understand the structure and characteristics, describing the main factors affecting it, the types of IPOs and the pros and cons of the transaction. This section is also focused on the choice regarding the market on which to complete the transaction, the aspects in favor of listing on the foreign or local market with a particular focus on the NASDAQ Market. This will be followed by a discussion of the roles of parties involved in the process and the various stages into which the IPO is divided.

2. Chapter II, on the other hand, contains a brief presentation of biotechnology, describing its functions and categorization. Following, this section includes a detailed description of the listing operations carried by biotech companies, highlighting historical data and trends, the years of greatest and least expansion and the significance of this phenomenon. Another point of discussion is the characterization of the global biotech market and the growth trend that it is going through with all its implications for operating companies in terms of competition, strategies of differentiation and risks involved. The chapter ends with an in-depth comparative analysis

between, the USA market, being the most relevant market on a global scale, with the Italian local market.

3. Chapter III presents Genenta Science S.P.A Case Study, the only Italian company listed on Nasdaq. The main objective of the company is to develop an innovative technology to be used in cancer's treatment. This section starts with a description of the company's history, mission and vision with particular regard to the events most relevant to its development. After that we'll briefly discuss the company's financial structure and its financial planning. We will provide an overview regarding the listing carried out by Genenta in the NASDAQ market. Finally, we will argue about a comparative analysis between Genenta's stock price performance and other biotech companies listed on NASDAQ. The analysis will be used to better understand whether is it worth investing in one of the fastest-growing and most promising sectors in the near future.

Chapter One

1. Initial Public Offerings

1.1 General Features of IPO

We begin our analysis by starting with identifying and explaining what is meant by IPO, or Initial Public Offering, is a process through which a private company becomes public for the first time by selling its shares to the public from this time becomes listed on a stock exchange.

From a capital owned by a single shareholder or several shareholders, the company, through listing on the stock exchange, opens to a wider audience of investors. The so-called free float is created by making available to the investors a specific number of securities, prescribed by the regulations for admission to the Stock Exchange.

The decision to go public can be one of the most important in a company's history and one of the most challenging, a company in fact needs the assistance of experts to stage a successful IPO. (Pagano, Panetta, & Zingales, 1998) stated that *going public is a decision rather than merely a stage in the life of a company.*

The company known as an 'issuer' with the help of some players like investments bank offers its shares to the public that can be traded in the open market.

To do so the company must enter in a particular stage of its growth process, it must be mature enough to deal with the strict regulations of regulators like the Securities and Exchange Commission "SEC", only at this point it can advertise its interest in a listing. It is expected behavior for a firm that wishes to undertake an IPO to start acting as it is a public company, already in the two years that precedes the IPO. A private company must be ready on time.

The listing brings benefits not only from a financial point of view, but also in terms of reputation and governance. For high-tech firms' funding equity capital via IPO could be a more efficient way to finance their most innovative projects, especially as compared to debt funding. This is due to greater uncertainty about returns of high-tech investments compared to traditional sectors, which could lead lenders to raise interest rates.

As we said being listed on the stock exchange is one of the most important initiatives in the life of a company producing a series of short term and especially long-term effects. This decision can respond to various reasons, some of the most common are:

- To raise equity capital to finance major growth programs having access to capital market
- To increase liquidity for a firm's stock, which may allow owners and employees to sell stock more easily and monetize their investment.
- To compensate employees with public company stock and stock-options.
- To improve commercial position through brand awareness, greater visibility that according to (Maksimovic and Picher, 2001) can increase corporate prestige and consequently bargaining power.

On the other side, before deciding to become a public company, there are important factors to consider:

- Going public will take time and money to accomplish.
- The company has to face significant new obligations, such as filing SEC reports and keeping shareholders and the market informed about the company's business operations, financial condition, and management which is costly and time consuming.
- Possible loss of flexibility and control of the company, particularly when public shareholders must approve the company's actions.
- Information about your company, such as financial statements and disclosures about material contracts, customers and suppliers, will become available to the general public, also to the competitors.

Once the company has made the decision to go public and chose the market where should be listed, the company must be informed of the different types of IPO.

The IPOs are generally divided into two types: Book Building and Fixed Price in which the major difference between these IPOs is the price offered to investors.

In the Fixed Price, there is only one price, and all investors need to apply at that price only.

In a Book Building issue, there is a price band and investors have the option of bidding at any rate between the price bands, it is the most used method.

Although these are the two most common forms of IPOs, they can be further classified depending on how a firm chooses to go public. Some other common methods are:

SPAC

SPAC is the acronym for "Special Purpose Acquisition Company", this method became popular in the last years, booming in 2020 during the coronavirus pandemic due to uncertain market conditions. This type of IPO process is much quicker for a company than the traditional IPO

method since a private company has to find a SPAC, already listed, to make a deal with and become a public company.

Direct Listing

In this type of IPO there are no underwriters, cutting out the middleman makes the process cheaper and faster. It is an ideal method for established companies with a loyal customer base since can save money and avoid diluting existing ownership since existing employee and investor shares are listed directly onto the stock exchange.

Reverse Merger

Reverse mergers are like the SPAC with the difference that instead of the getting acquired, the private company is the one doing the acquiring. In this process, a private company merges with a "shell company," already listed.

Figure 1 - "Global IPO activity from 2013 to Q1 2022"

Source: EY, Dealogic "2021 EY Global IPO Trends report"

Given the pros and cons we can say that the phenomenon of IPO in the recent years had a very particular trend, with 2,388 deals raising US$453.3b, 2021 became the most active year for IPOs in the past years as shown in **Figure 1**, the global IPO activity was up 64% and 67% by deal numbers and proceeds, respectively.

It is worth noting the record capital raised by the NASDAQ that dominated the listing exchange segment in USA in 2021, with 97.5$ billion raised, representing an increase of 85% from 2020 and more than 300 IPO deals completed.

This revival of the stock market at a global level, is mainly due to the pandemic crisis, that brought a significant growth in the raising of capital, through both new listings and capital increases by companies. Another reason for this incredible success is the fact that the markets were significantly less volatile in 2021 providing a less unpredictable backdrop compared to 2020 and therefore a perfect environment for IPOs. This phenomenon has mainly affected the Americas that continued to be the first region contributing to 39% of global proceeds, while Asia-Pacific growth was, relatively, modest. The EMEA region saw the highest relative year-on-year growth with an increase of about 214%.

After this record-high levels of global IPO activity in 2021, volatile market conditions have resulted in a significant slowdown during the first quarter of 2022. For Q1 2022, the global IPO market saw 321 deals with a decrease of 37% Quarter on Quarter, raising US$54.4b in proceeds decreasing 51%. Some of the factors that led to this decline can be found in the rising geopolitical tensions, stock market volatility, price correction in over-valued stocks from recent IPOs and rise in inflation.

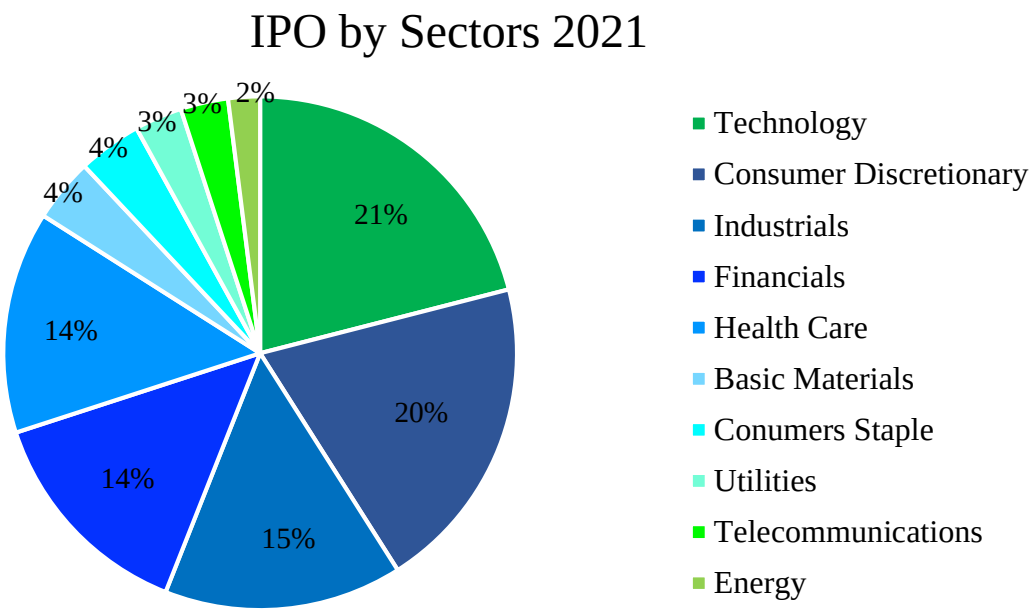

Figure 2 - "IPOs proceeds by sector in 2021"

Source: Dealogic, Bloomberg "Global IPO Watch 2021"

Moreover, the first quarter saw some slight shifts in sector performance partly due to the changing economic environment and market conditions. Technology with 21% of IPO activity by capital, Health Care, and Industrials with respectively 15% and 14% led 2021 sector IPO activity as shown in **Figure 2**, with a slight increase in the Energy and Telecommunications sectors.

1.2 Choice of the Market and Requirements: The Nasdaq Market

For the listing, the choice of the regulated market on which to carry it out is of fundamental importance; this choice refers both to the geographical position of the market (domestic or foreign), and to the type of market. With reference to the geographical position of the market, a company tends to choose the stock market situated in the country in which it has the greatest commercial interests or intends to increase its visibility. With reference to the type of market in which to apply for admission, it is necessary to valuate considering any sectorial or dimensional segmentation, operating mechanisms, levels of liquidity, listing times and costs, the number and articulation of financial intermediaries and institutional investors present in that market. *The stock exchange provides liquidity and determines a market price for public companies' shares, which is not easy for private companies. Liquidity benefits investors who can, therefore, buy and sell securities quickly and easily* (Berk & DeMarzo, 2016).

Listing on foreign markets can have positive and negative elements for the company. In the first place, it is more complex, and it implies additional costs due to the constraints of a securities law and market regulation that is different from the national one and due to the burden of having to maintain relations with the management authority. On the other hand, however, the operation can also be carried out with the desire to establish relations with foreign companies by also demonstrating a strong corporate interest in operating in their country.

Large IPOs take place on the stock markets, defined by Duguid as "the market of the world " The main markets globally as also displayed in **Figure 3** are: NYSE, NASDAQ, LSE, Borsa Italiana.

- **The New York Stock Exchange**, (NYSE), which is the world's largest stock exchange by trading volume and the second largest by number of listed companies with a market capitalization of more than 27000 billion dollars.
- **The London Stock Exchange** (LSE), with the index FTSE 100 is one of the biggest exchange with a market capitalization of 4000 billion dollars.
- **The Borsa Italiana,** regulated by the “Commissione Nazionale per le Società e la Borsa” known as CONSOB and has a market capitalization of 3000 billion. The FTSE MIB Index

is a major stock market index which tracks the performance of 40 leading and most liquid companies.

- **The NASDAQ** stock exchange is a U.S. based stock market exchange. It is currently the second-largest stock exchange globally with a capitalization of 21000 billion dollars, second only to the NYSE.

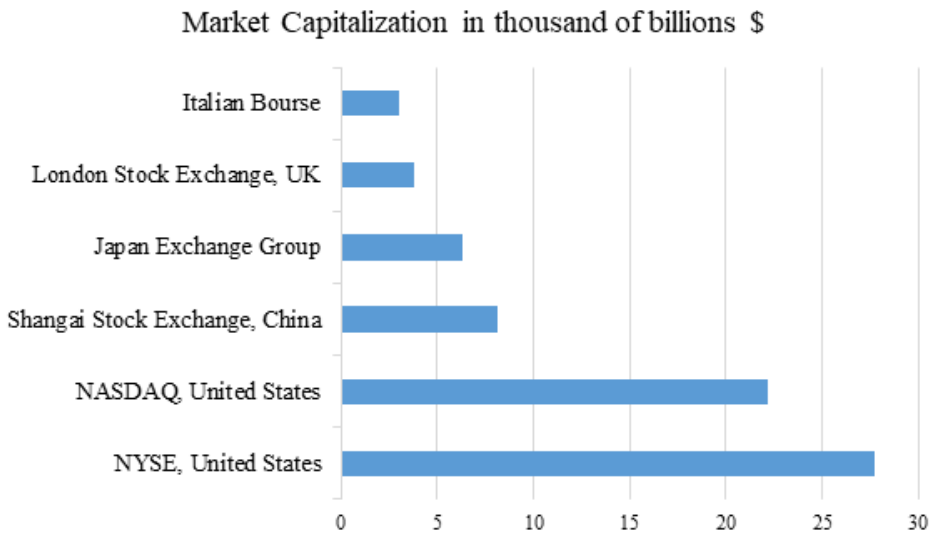

Figure 3 - Chart of the main stock exchanges globally per market capitalization.

Source: data collected on Statista.com, 2021

The "National Association of Securities Dealers Automated Quotations" better known as NASDAQ, was established on Wall Street on February 8, 1971, and was the world's first exclusively electronic stock exchange. Originally, computers only served to disseminate price information continuously and not to connect operators, the passage of orders was in fact via telephone until 1987. The diffusion of quotations via telematics, however, guaranteed a considerable increase in transparency and market efficiency: Nasdaq for a long time was the stock market where spreads were lower.

The fully electronic transmission of orders was also established at the end of 1987. During the market crash in October of that year it became clear, in fact, that the collection of orders by telephone was unsustainable: due to the large number of incoming orders, traders and dealers could not physically answer the phones and the lines often dropped.

Currently on this market more than 3000 different companies are listed, in some cases with more than one class of shares, many of them belonging to the technology sector since the index

considered the main reference for all the securities of the technology sector. The Nasdaq is therefore the list with the largest number of companies present in the United States.

From a technical point of view, the NASDAQ is characterized by the presence of operators required to continuously provide a bid-ask quote for the securities for which they are registered as market makers. Due to this structure the exchange is well known for the high-volatility trading that takes place in its electronic marketplace.

NASDAQ Inc. continues to innovate expanding its business lines beyond a stock exchange, focusing on applying technology to finance.

Companies listed on the NASDAQ are grouped into three different tiers based on market cap and each have their own listing requirements, these are:

- **Capital Market** is a market for companies wishing to raise capital that have a smaller levels of market capitalization and with the least stringent listing requirements.
- **Global Market** is the market for companies that operate internationally.
- **Global Select Market** has the most rigorous listing requirements regarding in particular corporate governance and liquidity standards of all three tiers and features mid-cap and large-cap stocks.

Within the stock exchange the main indexes are the NASDAQ Composite that represent the whole stock market and within it the NASDAQ 100.

The Nasdaq Composite is the main index used on the NASDAQ; it is based on free float capitalization that summarizes the performance of the stock exchange. Its total value is given by the sum of the weights of each stock that makes it up multiplied by its price. The result is then divided by a correction factor that makes it more manageable in reporting.

Within the NASDAQ Composite there is the NASDAQ 100, which is a market-value-weighted index of the top 100 non-financial stocks on the stock exchange and it accounts for 90% of the movement of the NASDAQ Composite.

The most represented sectors are technology (hardware and software), telecommunications, biotechnology and retail and wholesale trade.

Also, the Nasdaq 100, like the Nasdaq Composite, is an index based on market capitalization, even if in the calculation of the distribution of the weights a particular algorithm is used that takes into account the sector in which the listed companies operate, to guarantee a certain diversification that allows all the product sectors to be considered.

The Nasdaq 100 undergoes quarterly revisions that can determine the change of the listed securities or the modification of the relative weightings.

Some of the requirements to join the Nasdaq 100 are: securities must have a daily trading volume of at least 200,000 pieces. An average total market capitalization of 0.1% or more of the average market capitalization of Nasdaq 100 securities is also required, and companies must have been listed for at least 2 years.

1.3 Organization and Subjects Involved

Since IPOs are particularly complex and time-consuming processes, the selection of the right team composed by specialized operators and advisers is essential to operate in a professional and coordinated manner. The company must establish a collaboration with different actors, these are generally: financial advisers, credit institutions, securities brokerage firms, auditing firms, legal firms and communications consultants, who work alongside the listing company throughout the admission process and for the period after the start of trading. Their number and involvement may vary according to the complexity of the transaction and the needs of the company.

Depending on the size of the IPO, the number and involvement of the different subjects may vary, in the case in which the underwriter is alone it is called the sole manager, if instead there are many underwriters, they are directed by the lead underwriter, a banking firm responsible for managing the deal, often called the book-running manager. Underwriters are chosen based on their reputation and their experts' quality in the sector they belong to.

In details the main actors are:

- **The sponsor**

  The Stock Exchange Regulations provide that the company applying for admission to listing must appoint a sponsor appointed by the company. Its task is to "present" the company, guaranteeing the quality, the accuracy and completeness of the information provided by the company to the market and to the Stock Exchange. The role can be carried out by banks, investment companies.

  The sponsor must undertake to publish at least two financial analyses a year on the company and organize meetings between the company's management and the financial community.

- **The Global Coordinator**

  The subjects that perform the role of global coordinator of the offer are investment banks, they play a crucial role taking care of the coordinated execution of all the phases of the process, from the listing to the offering of securities. The global coordinator directs the placement of the securities on the market and influences the levels of demand through the definition of the pricing and the marketing activity with institutional investors. Moreover, he supports the company in the preparation of the documents necessary for the listing.

- **Legal advisors**

  The main function of the legal advisors is to assist companies, shareholders and intermediaries in relation to the legal, contractual and regulatory aspects of the listing. Specifically, the legal advisors oversee the drafting of all the documentation related to the shareholders' resolutions concerning the listing process, the legal due diligence and all the documents concerning the application for admission and the offer.

- **The communication companies**

  The communication company is responsible for external communication regarding the corporate image and the operation. It oversees the organization of all mandatory or optional communications in the pre-listing phase, as well as road shows and presentations to banks. The support activity continues also in the post-listing phase since the flow of information with the financial community and investors remains of primary importance.

- **The financial advisor**

  Listed companies are also assisted by a financial advisor, a trusted advisor of the company who assists it both in setting up the operation and in choosing other advisors. Other than a general advisory support function, the advisor also provides support to the issuer in defining the terms of the offer, in drafting the prospectus, the business plan and all the documentation to be submitted to the regulator and the financial community.

- **The auditing firm**

  Which audits and certifies the financial statements of the listed company, collaborates in the drafting of the prospectus and prepares comfort letters for the sponsor and the global coordinator in which they express their opinion on the business plan.

- **The SEC**

  Having the role to protect investors, maintain fair, orderly and efficient markets and facilitate capital formation, will also play a significant role in the IPO process. Keeping in mind the impact that the SEC can have on the company's registration process is important when choosing advisors who will assist in the IPO process.

1.4 Phases of the Process

The first step as we said before is the team selection (financial advisor, legal team, sponsor etc…) in the preliminary phase, then the team is dedicated to preparing a prospectus and submitting it to the SEC for approval. The third stage is represented by the company`s presentation through the so called "Roadshow" to investors, especially institutional ones. Then the company has to face a complicated task consisting in the pricing and the declaration of how many shares will be issued. The chart below represents the phases that generally characterize an evaluation finalized to the quotation in the Stock Exchange (**Figure 4**).

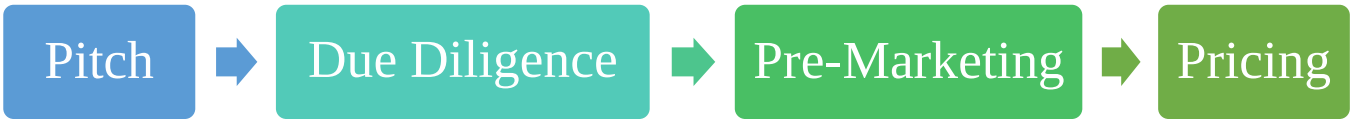

Figure 4 - Main phases of IPO's process

Now we can analyze the different phases more in detail.

Pitch (Preliminary phase)

The preliminary phase represents the moment in which the company, approximately 4-5 months before the conclusion of the listing process, will choose the Sponsor and the Global coordinator that will support it for the whole process. In this phase the banks will submit a proposal to receive the assignment, generally containing a preliminary assessment of the company to be listed.

Due Diligence and preparation of offering documents

The second phase consists in the due diligence and the preparation of the offering documents, this process involves the Economic-financial, patrimonial and legal sectors. The sponsor and the

consultants must carry out an in-depth analysis of the company, identifying the critical success factors and all the elements necessary for an evaluation of the feasibility of the listing and the value of the securities to be issued. In this phase, the global coordinator will proceed with the preparation of the documentation for the meetings of the Board of Directors for the Shareholders' Meeting and to present an initial assessment of the company drafting the Prospectus which *is a legal disclosure document that provides information about an investment offering to the public, and that is required to be filed with the Securities and Exchange Commission (SEC) or local regulator. The prospectus contains information about the company, its management team, recent financial performance* (Corporate Finance Institute).

Pre-listing marketing activities

During the pre-marketing phase, carried out one month before the listing, the lead bank will conduct a survey of institutional investors aimed of accumulating "declarations of interest" from institutions and brokers. The purpose is to obtain an indicative price range for the securities to be placed, the final number of shares and their allocation among investors. Once the Prospectus is presented and accepted, the roadshow starts.

Roadshow: are a series of meetings in major financial centers where the management present themselves and the company's key figures to potential investors, with the aim to increase interest in the company's investment case.

Pricing

To establish an offer price for the new issued securities, the company must be valuated through different process aimed at estimating the value of the company. The main methods of valuation are:

The Discounted Cash Flow method

The Discounted Cash Flow method, often referred as with its acronym DCF, it is the most used and supported method by modern business theories, *is a method to estimate the real value of a firm.* (Quiry, Dallocchio, Fur, & Salvi, 2014). The concept is based on the fact that the economic value of any company corresponds to the present value of the cash flows available that the company itself is able to generate in the future.

Through this methodology, a company is evaluated based on its effective ability to create value by comparing outgoing cash flows with incoming ones and discounting this result using the weighted average cost of capital (WACC) for the discount rate.

The Multiples method

It is another important alternative approach to those based on quantities flow and consists in the analysis of the market price of the shares of a sample of comparable listed companies to the company being evaluated. This methodology is probably the quickest way to value a company and it based on the general assumption that the share price represents the best approximation to express the economic value of a company.

There are several key company multiples used in the valuation, including:

- Price/earnings ratio (P/E): the ratio of share price to net income per share.
- EV/EBITDA: the ratio of Enterprise value to EBITDA.
- EV/EBIT: the ratio of Enterprise value to operating income.
- EV/Sales: ratio of Enterprise value to corporate revenue.
- EV/OFCF: ratio of Enterprise value to operating cash flow.

After applying one of the two main valuation methods or a combination of the two that can obtain a better estimation, arrives at the definition of the so-called fair value of the economic capital of the listed company.

At this last point we have the Book building finalization where potential institutional investors communicate to the book runner the number of securities they intend to purchase and the price they intend to offer and, based on the orders collected, the price and the offer quantity of the placement is fixed.

Price fixing normally takes place in 2 stages:

- the shareholders' meeting approving the capital increase sets a range
- the General Meeting approving the capital increase sets a preliminary price range that is sufficiently wide to take account of any changes in market conditions.

Based on these results, the placement price for the launch of the IPO is determined.

Chapter Two

2. Analysis of the Biotech Industry

In this chapter we are going to analyze more in detail the Biotech Industry, starting from a brief presentation of the biotechnologies, we'll describe the different types of funding for a company operating in this sector, highlighting the IPO. Then it will focus on the global market situation, analyzing the future trend, concluding with a comparative analysis of the two target markets, the Italian and U.S. market.

Biotechnology is a science that jointly uses living organisms and biological systems to develop products and processes to improve the quality of life. It applies scientific knowledge to the processing of biological agents. More precisely, ENEA, Assobiotec and Federchimica in the BioinItaly report 2019, define biotechnology as "technologies that control and modify the biological activities of living things to obtain products on an industrial and scientific level".

The history of biotechnology begins with agriculture, then evolving over the years with genetic engineering and DNA and the treatment of certain diseases. With the development of technologies and needs, this sector has undergone further developments.

Biotechnology can be divided into different types according to the field in which they operate:

• **Red** biotechnology is applied in the medical field; it stands out for its genome studies. Its primary application is innovatively designing a drug to allow the medicine to reach the target while avoiding the immune system's attack. Another application can be identified in the gene therapy, and the study of DNA to develop cures for genetic diseases; Red biotechnologies are the most recent and innovative. They originate with an alliance between pharmaceutical companies and biotechnology companies, creating the biopharma niche market.

• **White** biotechnology used mainly in the industrial sector biology to produce a commercial or mass consumer product like solvents. The basic principle is to exploit enzymes and this type of biotechnology is mainly used in sectors such as food, energy, cosmetics, etc.

• **Green** biotechnology is applied in the field of agriculture. Some applications can be found in the development of biofertilizers and biopesticides, whose purpose is to limit the environment's impact

while maintaining traditional effectiveness. Applying biotechnology to crops can also make farming more attractive to the market as it can increase pest resistance and increase storage times.

One particular branch of biotechnology is the medical biotechnology, dedicated to the development of active ingredients, the production of vaccines and the development of new techniques for the analysis and diagnosis of diseases and related gene and cell therapies. More specifically, they see the application of biochemistry, microbiology and genetic engineering to produce goods and services in the medical-pharmaceutical field, for the diagnosis and treatment of diseases.

Although valuations of the life sciences sector over the past year have been mixed, the underlying performance and outlook for the sector is healthy. *The growth of many companies has been sustained by the tremendous efforts made to accelerate the process of testing and approving new drugs against COVID-19, and most others have remained fairly unaffected by some of the impacts of the pandemic that were initially feared (e.g., the slowdown in patient recruitment and study execution)* (World Health Organization, 2022).

It is expected further growth since life sciences companies continue to transform.

Nothing has had such a drastic impact on biopharmaceuticals as the Covid-19 pandemic. Health and life sciences companies have stepped into the spotlight as prevention, treatment, and vaccination against the virus have taken center stage. Meanwhile, the clinical trial and drug approval stages have become topics of conversation. Public attention to life sciences has brought financial benefits to biotechnology, previously disinterested investors have begun to see the value of this sector, making new funds and more capital available.

Many life sciences companies have grown and strengthened with stronger balance sheets to invest in. Digital transformation has accelerated every part of the life sciences value chain; in 2022, visionary leaders will continue to drive investments focused on strategic, long-term digital goals, using automation, smart factories, and artificial intelligence to transform manufacturing and new technologies to build supply.

2.1 Types of funding and IPOs in the Biotech Market

As mentioned above we have different types of biotechnology, which aim to provide innovative projects that need funding to be developed. Biotech companies have typically three paths to raise money for the research and development stage.

Licensing is the primary trend, consists in license out the drug discovered to a big pharmaceutical company, this method benefits both the biotech company and the big pharma firm since both collaborate using their different capabilities. Generally, the biotech company has an innovative product but lacks the skills to market and distribute a drug. On the other hand, a large pharmaceutical company possesses the marketing and sales capabilities but often lacks highly innovative products in their pipeline.

For this reason, licensing is one of the most used and an excellent method for funding that favors both sides.

Another way for a biotechnology company to raise money can be found in M&A. The biotech firm becomes the target company for the acquisition by a big pharma company. Indeed, the latter usually has a large cash reserve that the biotech firm does not have and is willing to pay a premium price to acquire the company. Mergers and Acquisitions promote the synergy of the two companies. The advantage of a biotech firm in completing a transaction is the increasing of shareholder value.

A biotech firm's last possibility is to get listed on a stock exchange and raise money with an Initial Public Offering. In this way, the company will receive the necessary funds from investors to carry on its drugs to market on its own. As discussed in the previous chapter, initiating the IPO process is costly, and only the biggest firms can go through it. A biotech company can be backed by Venture Capital that provides funds for developing a drug mainly in the first phases, while also taking the risk. George Rathmann, founder of Amgen Inc. one of the first biotech company in the market, believed that a better way to finance the company was to have an initial public offering (IPO). More specifically the IPO activity in the biotech sector has grown faster than any other category of fundraising in the last years, with companies raising $34.3 billion in 2020, an increase of 186% with respect to the previous year. Although US biotech's represented the lion’s share of IPOs, companies based.

According to Refinitiv, 84% of listings by biotech and pharma companies were made on their home market between 2017 and 2021. *In many cases, this could be attributed to the close ties that those issuers had established with their home countries, culturally, economically, and in terms of their fundamental infrastructure* (Baker McKenzie, 2022). However, the appeal of cross-border listings is growing particularly between biotech and pharma companies. Biotech in fact tends to source opening capital from their local stock market, with the United States (mainly NASDAQ) being the preferred nonlocal option but also China have seen significant growth in the past years.

The biotech sector is an industry entailing high returns; therefore, high risk. *The process from discovering a drug to approval is lengthy and costly, on average, only one drug over 5000 reaches the FDA approval* (Kallmeyer and Canabou, 2001).

Since most biotech IPOs have drugs that are in the development stage, the analysis of the stock is based on the potential outcome of pending research so it can be extremely risky and require lots of research. Some of the factors to look at in biotech companies are: Market potential, Pipeline, Resources, Research and development (R&D), Scientific advisory board (SAB), Experienced management, Debt, Burn rate.

The trend of biotech IPOs reached a record in 2021 with both the number and proceeds reaching all-time highs completing 96 IPOs proceeds in a year. For the biotech IPOs, 2020 was an important year too, 77 companies went public in with a 77% increase from 2019.

The highest earner of the year was Sana Biotechnology, a preclinical cell engineering biotech that raised $676 million in proceeds and eventually reached a valuation of $6 billion after listing.

Biotech IPO gross proceeds also increased sharply, from $5 billion in 2019 to $12 billion in 2020, as we can see there has been a real rush to take advantage of this propitious moment. Most biotech companies that pursued IPOs in 2020 were small, 87% of the companies have a revenue under 50 million dollars.

There has been an overwhelming supply of preclinical biotech going public. But according to Jordan Saxe, head of healthcare listings at Nasdaq, preclinical IPO trend is likely here to stay, the companies have two routes: either they produce “really interesting data” with their first readouts, or they falter in the clinic and “have to deal with that in the public markets.”

Companies listed on Nasdaq market classified as biotechnology or pharmaceutical industry have a dedicated index, the Nasdaq Biotechnology Index “NBI”.

It was launched on November 1, 1993 and historically the Index zoomed almost 700% up to its peak in March of 2000, only to experience a dramatic fall along with the rest of the Tech equity bubble and a lost decade of subzero returns. Recently, as shown in the **Figure 5**, after a strong growth up to 2021 the index plummet to the original values in 2022.

Figure 5 – Nasdaq Biotechnology Index Chart 2020-2022

Source: Investing.com

The NBI is constituted by 370 companies, the top 5 represent approximately 32% of total market cap. The largest of these is Amgen (AMGN) with a market cap of $144Bn, followed by Gilead Sciences (GILD), Moderna (MRNA), Vertex Pharmaceutical (VRTX), and the last one is Illumina (ILMN) with a market cap of $56Bn.

Some of the requirements of the index are:

- Companies must be classified as Biotechnology & Pharmaceuticals by the Industry Classification Benchmark.
- The minimum market capitalization is $200 million.
- Average daily trading volume of at least 100,000 shares.
- Companies must be listed on Nasdaq.

In the US in 2021 there have been 109 IPOs of Biotechnology firms, all of which listed with Nasdaq. Collectively, these listings raised $21.5Bn. Nasdaq's market dominance in attracting biotech IPOs over several decades has resulted in an overall market share of 98% of current listings including 7 companies large enough to warrant inclusion in the Nasdaq-100 Index. In 2019, a net of 4 companies were added to the NBI, whereas a net of 84 companies were added in 2020.

2.2 Global Situation and Future Trends.

Scientific evolution is an unstoppable process. Each evolutionary leap is accompanied by revolutionary spillovers in health care. Thus, in less than 40 years the biotech applications in

medicine have gone from 'simple' replication of natural cellular mechanisms for the production of therapeutic proteins to tissue engineering, 'surgical' correction of pathologies written in DNA, and the development of ultrafast diagnostics that exploit artificial intelligence.

Some analysts believe that the biotech industry today is where the computer industry was 30 years ago poised for substantial growth. Because of the highly technical nature of the industry, it's difficult to pinpoint the companies and products that will be the first to emerge. (Taulli, 2012)

If biotechnology lives up to expectations, it could revolutionize modern medicine and, in the process, create significant opportunities for investors.

Biotechnology is defined as a "Key Enabling Technologie" (KET), it is characterized by:

- High dependence on developments in the science base of reference, having close links with Public Research Organizations, Universities and Research Institutions.
- Must possess in-house expertise, continuously fed by internal R&D investments, enabling them to "absorb" knowledge from external sources and manage innovative "open innovation" models.
- Use of formal property right such as Patents for industrial invention, compared to other productive sectors, to appropriate innovations and defend their competitive advantage
- Rapid innovation cycles

Biotech has historically been concentrated in a limited set of countries like United States and China because it depends on clusters of innovation that exploit existent academic and technological communities, but countries are looking to lure both firms and talent to catapult their domestic industry firms competing for the best biotech talent.

As shown in **Figure 6**, the US is the largest biotechnology market globally by far, accounting for 39.4% of the global market's total value in 2020. Comparatively, the entire Asia-Pacific and European regions accounted for 32.5% and 20% of the global market's value respectively. The performance of the US market has a significant influence on the performance of the global market overall.

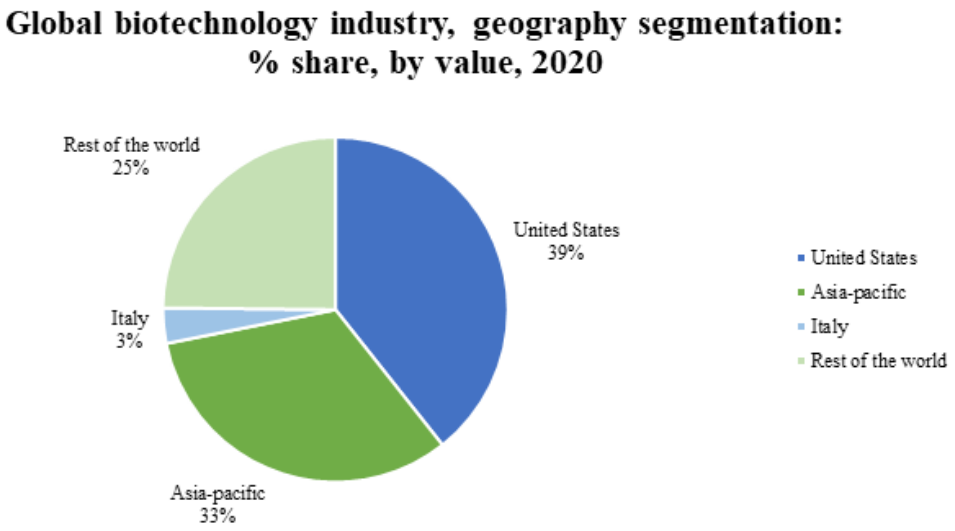

Figure 6 - Global biotechnology industry by geographic segmentation.

Source: MarketLine, "Biotechnology in the United States Industry report, October 2021"

According to research carried out by EPO Worldwide Patent Statistical Database (PatStat) in 2007, with reference to the decade '97-'07, the country with the highest number of inventions in the biotech sector is the USA, followed by countries belonging to the OECD (Organization for Economic Cooperation and Development), mainly Germany and Belgium.

Since patenting is expensive, European countries and the U.S. are on top of the list, while Asian or South American countries may not have the necessary funds. However favorable government initiatives are leading the growth of biotech sector in developing economies such as China, India, Brazil.

Several initiatives are being taken by the governments to promote the industry in particular government policies aim to improve the drug regulatory process, standardizing clinical studies and accelerating the product approval procedure. These strategies would incorporate novel technology platforms and benefits in improvising biotech products accelerating market advancement. In addition, biotechnology organizations are focusing on the development of systems can be patented and leveraged in collaboration with market participants. In Europe and important cluster was created between Denmark and Sweden, Medicon Valley, is one of the most relevant. It was created with the intention of developing the interconnection between companies in the biotechnology, and to facilitate their flows.

The global biotechnology market experienced strong growth in the historic period, but slowed down slightly in 2020, recording growth of 6.6% YoY. In the last 2 years as we can see in **Figure**

7, the global biotechnology market as seen a strong growth again reaching an all-time high with a total market value exceeding 300.000 million dollars.

The emergence of the Covid-19 has driven the market, bringing new attention to the healthcare sector, and companies are developing new solutions for combating the pandemic situation.

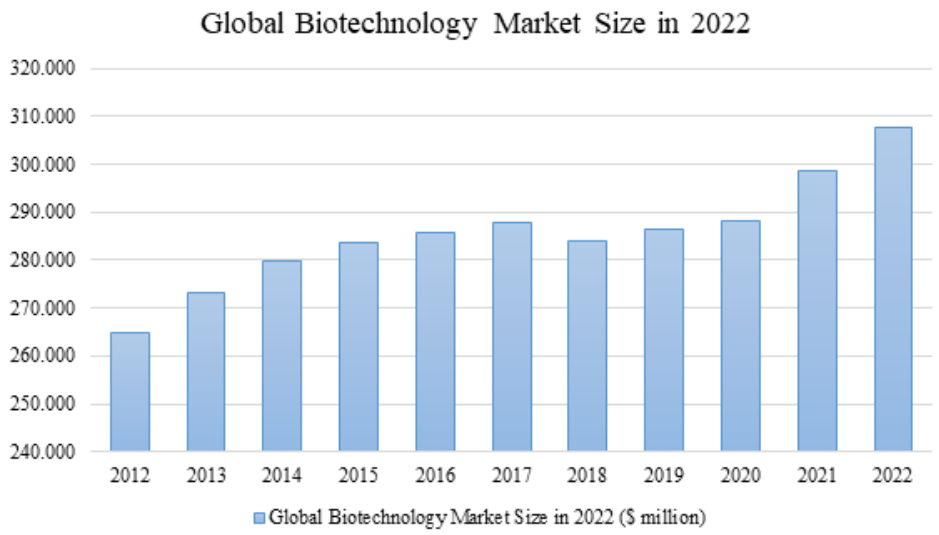

Figure 7 – Global Biotechnology Market size from 2012 to 2022.

Source: IbisWorld, "Global Biotechnology Market Size, May 2021"

Biotech is expected to have a bright future. As the global population ages, there will be strong demand for new drugs. Japan, Asia-Pacific's second largest biotech market (after India), is home to the world's oldest population. Approximately a third of its residents are over the age of 65, a figure that is expected to increase to nearly 40% by 2040, according to the National Institute of Population and Social Security Research of Japan. This will necessitate new and innovative treatments for the increased prevalence of age-related illnesses, supporting market growth.

During the next 20 years, biotech is likely to transform a broader range of human experiences.

A more multidisciplinary, digital, and data-rich approach to life sciences is accelerating the process. Although market, regulatory, and normative conditions will moderate the pace and focus of progress.

Eradication of most common diseases may be possible in the future, driven by a range of biotech advances, including disease vector control and the Artificial intelligence (AI) and device study techniques that will increase the efficacy and performance of studies, reducing the time and cost of launching new treatments.

On the other hand, real-world execution is unlikely to match the theoretical health potential because of uneven global access to these technologies within this period.

Regulatory Restrictions could prevent or reduce funding, production, or public acceptance of biotech, in fact bans, restrictions, or modification of standards could emerge in response to accidents, unintended consequences, or public pressure. More restrictions could reduce the number of people choosing to enter the field, leading to greater competition for personnel and shortages of expertise.

According to a new report by Grand View Research, the global biotechnology market size is expected to reach USD 2.44 trillion by 2028. It is expected to expand at a CAGR of 15.83% from 2021 to 2028. The factors driving the market include a strong and steady government funding and favorable government policies, the launch of new and advanced products, and rising demand for synthetic biology.

The main future trends are: Nanobiotechnology, Bioprinting, Tissue engineering within them In particular the Oncology is the one that deserves a more detailed analysis being in strong growth, and one of the most promising.

The "traditional" ways to treat cancer are chemotherapy and radiotherapy. One big problem with these techniques, is the lack of specificity as they are targeting cancer cells, but also healthy cells. Increasingly numerous in laboratories studying cancer, biotechnologists are now the key players in research that combines knowledge of classical biology and new technologies.

Working on DNA with living systems such as human cells, viruses and bacteria has enabled researchers around the world to identify genes involved in the formation and growth of tumors and to devise strategies to turn them on and off as needed, but it has also made it possible to identify molecular targets to hit diseased cells without harming surrounding healthy ones reducing dramatically the side effects. It also uses the immune system to block cancer from relapsing in the future, and so this strategy enables a treatment that is not just toxic curative. We saw that biotech drugs fight cancer in a better way than classical chemical drugs do. It is precisely thanks to biotechnology, in fact, that giant footsteps have already been made in the treatment of many cancers.

The future of cancer treatments will therefore remain of utmost interest to the biotech industry as the levels of personalization, accuracy and efficiency of these treatments continues to improve, new very promising solutions are in various well-funded pipelines and should arrive on the market soon. According to data provided by Assobiotech (National Association for the Development of Biotechnology), more than 600 biotechnology drugs and therapies have been used to date to treat more than 100 diseases, and of these, more than 200 are used to treat cancer.

2.3 Biotech Sector Market Insights: USA Market VS Italy Market

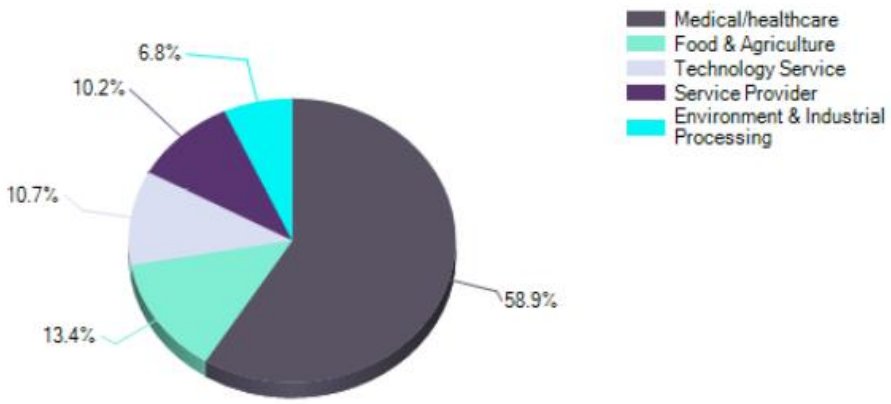

Figure 8 – United States biotechnology industry category segmentation.
Source: MarketLine Industry Profile Biotechnology in the United States, October 2021

Biotechnology and associated products are required to meet regulatory guidelines and pre-set standards, the industry in the U.S. is regulated at the national level by the Food and Drug Administration (FDA), which regulates the development, production and marketing of biotech therapeutics in the health sector and is the most important body in the world for this industry the Environmental Protection Agency (EPA), the National Institutes of Health (NIH) which is the primary U.S. government agency responsible for biomedical research.

Major Bio-Clusters are concentrated in: California (20%), Massachusetts (6%), Texas (5.4%). In the U.S., most companies in the industry research and develop products for the medical sector, which is the main demand segment and determines about 65.2% of the revenues of the biotechnology.

Analyzing the competitive environment of U.S. biotechnology market through a framework such as Porter's 5 Forces, it can be concluded that the market is mature, and there are many established international players such as Johnson & Johnson and AbbVie Inc. operating, as well as many biotech startups. Leading players benefit from large revenues, which allow them to invest heavily in research and development (R&D) to bring new, innovative products to the market. This however has created an intensely competitive environment, to decrease rivalry companies can differentiate their products by targeting a particular therapeutic area in the case of medical biotech, focusing on a particular niche.

Mergers, acquisitions, and partnerships, as also mentioned before, are a useful way of enabling leading players to expand their product portfolio and accelerate the development of new and innovative treatments. It is clear the strong trend toward concentration with acquisition of large companies to smaller players with patents for new products, but also increasing the number of industry players.

For example, in 2020 alone, J&J spent $7.3bn on acquisitions, with the goal of creating life-enhancing innovations and generating value through partnerships that will profoundly change the trajectory of health for humanity.

Biotechnology start-ups are typically spin-off companies, based on innovative products or processes resulting from discoveries in academic research. Such companies have long start-up periods with little profit; combined with high fixed costs, they must therefore secure a high degree of venture capital backing.

Market trends are expected to slow down, with a projected CAGR of 5.4% for the 2020-2025 period, which is forecast to bring the market value of US to 270.9 billion $ by the end of 2025.

The rise of the market in the US has been fueled by a number of factors, including the completely privatized system of healthcare, the emergency of Covid-19 and a high incidence of chronic diseases. (National Library of Medicine, 2020)

In the wake of the COVID-19 pandemic, which has brought the global financial system to a standstill and brought considerable levels of uncertainty to many sectors, the fate of biotechnology is uncertain. Demand for remedies and treatments has soared, but non-COVID studies and improvements (R&D) have been sidelined. Compared to the pharmaceutical sector, biotechnology companies will find it more difficult to catch up in the supply chain with new investments due to excessive R&D expenditure. However, in the medium to long term, the market as a whole should benefit from improved financing in the pharmaceutical sector, which is still its most important segment.

The new Biden administration is expected to support market growth, as it has committed to prioritizing innovation, transparency and diversity to reinvigorate the country's technological know-how and policy, which is likely to attract buyers and create an attractive management environment in which biotechnology companies can thrive.

After analyzing the U.S. market, we look in detail also the Italian market, whose reports on biotechnology development are offered annually by Assobiotec (National Association for the Development of Biotechnologies) and ENEA (National Agency for New Technologies, Energy and Sustainable economic development).

According to the most recent “Bio In Italy” report published by Assobiotec, the number of biotech firms operating in Italy has been steadily increasing over the past decade, reaching high of 790 in 2021.

The Italian biotechnology market had total revenues of $17.5bn in 2020, representing a compound annual growth rate (CAGR) of 17.5% between 2016 and 2020 as shown in **Figure 9**.

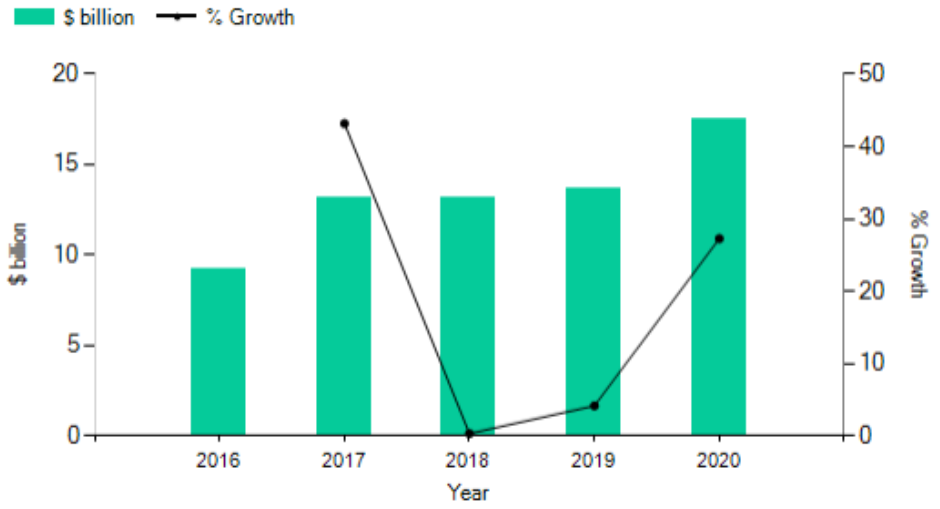

Figure 9 – Italy biotechnology industry value: $ billion, 2016–20.

Source: MarketLine Industry Profile Biotechnology in Italy, October 2021

In comparison, the main European competitors, French and German markets grew with CAGRs of 3% and 16.7% respectively, over the same period, reaching respective values of $6.0bn and $16.6bn in 2020. Italy established itself as a major competitor in the European biotechnology market. Italy is also home to a number of internationally renowned scientific research institutions, including the San Raffaele Institute of Milan, which has given rise to Genenta, a company that works on innovative treatments for cancer. This has established Italy as an attractive location for new biotech players. Italy is the 4th largest US Supplier Country in the Biotech sector with 4.2% share. In 2020, Italy exported $1,219.7 million worth of biotechnology products to the U.S.

Based on the data collected, the Italian biotechnology industry is confirmed to be a sector with a stable, when not slightly growing population of firms, characterized by a strong R&D intensity and peaks of excellence in all areas of biotechnology application. Investment in biotechnology research and development (R&D) by firms in the sector showed an acceleration in 2020 compared to the immediately preceding years, with a 7 percent increase over 2019.

The Italian biotech industry has yet to fully express its value and potential, this is demonstrated by the scarce presence of large leading groups with Italian capital like Recordati S.p.A., Zambon Company SpA or Menarini Industrie Farmaceutiche, in the face of many companies, often very innovative, but too small to establish themselves in the market. The Italian market in fact is more fragmented than its European counterparts, with an estimated 80% of firms operating in this market being micro or small biotech companies with 1-49 employees. As stated by Mario Coccia (Technovation): *"The key to stimulating the recovery of the business cycle is to support science and innovation through increased investment in research and development. These are the pillars that foster industrial competitiveness."*

Companies mainly active in the area of human health continue to account for the majority share of the total number of Italian biotechnology companies, considering the total number of enterprises, about three-quarters of the total turnover is produced by the health sector. *The growth of the medical/healthcare segment is driven by Italy's aging population and an increase in age associated disease, such as diabetes and cardiovascular diseases* (MarketLine, 2021).

The sector is characterized by a strong territorial concentration, the share of enterprises in the total of the top 4 regions (Lombardy, Lazio, Emilia Romagna, Piedmont). Expertise related to the development of new therapeutic approaches and diagnostics is particularly concentrated in the Northwest area of the country, driven by the presence of the small biotech valley in Lombardy, which alone carries out 43% of national research projects on therapeutics and 38% of molecular diagnostics projects.

Drug discovery and drug delivery activities, on the other hand, are equally divided between the Northwest (37%) and Central Italy (33%), driven in the latter area by the Lazio bioscience district.

From the data collected between 2017 and 2020, there is a steady growth of companies financed by Business Angels, while the contribution of Venture Capital grows especially in the last year of observation, (around 4 percent and 6 percent respectively in 2020), consistent with the findings of industry studies, and is mainly focused on the area of human health.

However, self-financing remains the main source of funding, the average round per investment in biotech is around €5 million, lower than the average cut for an investment in high tech biotech, which exceeded €6 million in 2021. Immediately following in importance is loan capital, consisting primarily of loans bank and the use of leasing about 30 percent and 10 percent relatively. Both instruments are used more by medium-sized enterprises.

Given the sector's high research intensity, a relevant role is played by public subsidies and grants, especially for research projects that account for about 17% of the sources of funding.

By analyzing the competitive environment of the Italian biotechnology market through a framework such as Porter's 5 Forces, it can be concluded that, having experienced strong growth historically, it is likely that in the long-term new players will be able to enter the market facilitating rivalry. In addition, the presence of large buyers increases the power of buyers, while poor differentiation among suppliers weakens their position.

Start-ups are expensive because of R&D expenditures, which require support from venture capital or large pharmaceutical companies, and government regulations are stringent. Barriers to entry remain high as companies have difficulty obtaining intellectual property rights to enter the market. The performance of the Italian biotechnology market has fluctuated in the period, experiencing very strong growth in 2017 but slowing down in 2018. The performance of the market is however forecast to decelerate, with an anticipated CAGR of 4% for the five-year period 2020-2025, which is expected to bring the market value to $21.3bn by the end of 2025.

Chapter Three

3. Listing On the Nasdaq Case Study: Genenta Science SPA

This last chapter consists in a more detailed analysis of Genenta Science SPA listing process on Nasdaq market, being the only Italian company reaching this extraordinary achievement, symbolizes a milestone for the Italian biotechnology sector and hopefully a turning point for our country. Initially, the company will be presented through a historical description, starting from its founding to the present day tracing its most significant events in its development with a focus on the listing on Nasdaq market, concluding with a brief report on its performance.
To increase the value and the reliability of this paper a personal interview was conducted to Pierluigi Paracchi, CEO of Genenta Science SPA, that we can find in the appendix. The most relevant parts or answers have been cited in this chapter, bringing a first-person account.

From San Raffaele in Milan to Nasdaq, with the goal of raising the capital to complete trials of a gene therapy to treat glioblastoma, a particular type of brain tumor. And from there, aim later to apply it to other types of cancer. This is the path between the past and the future of Genenta Science that has listed on the U.S. technology market "NASDAQ" where all the biggest biotech on the planet have their place.

"Genenta Science is the only domestic company to list on Wall Street on the U.S. tech list.
This is an important confirmation of the value of our research and entrepreneurial skills, and a further demonstration for the biotechnology sector of its willingness to look forward and commit to responding to the needs of patients and building a better future. The commitment and expertise of our companies, overcoming the limitations still present within the national ecosystem, prove successful in attracting interest across borders and in succeeding in raising significant financial resources. " – Riccardo Palmisano, President of Federchimica, ASSOBIOTEC, 2021.

3.1 History and Vision of the Company.

Genenta Science S.P.A is a pharmaceutical and healthcare company in a clinical-stage that develops gene therapies based on transcriptional and mRNA-mediated controls for the treatment of solid tumors. It was founded in 2014 as a spin-off of the San Raffaele Hospital (OSR) in Milan, a globally recognized premier research hospital for ex-vivo gene therapy, by Pierluigi Paracchi (CEO), Luigi Naldini (Chairman of our

Executive Scientific Board) and Bernhard Gentner (member of the Executive Scientific Board), to develop potential ground-breaking cell and gene cancer therapies.
Genenta was formed as an Italian limited liability company (società a responsabilità limitata, or S.r.l.). In May 2021, changed the legal form of the company under Italian law to a joint stock company (società per azioni, or S.p.A.) and also established Genenta Science, Inc, a Company under the laws of the State of Delaware (USA), a wholly owned direct subsidiary and intended for future operations in the United States. Genenta is headquartered in Milan, Italy, in an Alexandria Center's Launch Labs in New York, all top management, apart from the CEO, is based in the US.

The company can leverage the vast experience in LVV (Lentivirus Vector) technology of the San Raffaele Telethon Institute for Gene Therapy (SR-Tiget). This platform was developed in the SR-Tiget laboratories of the founders, Prof. Naldini and Dr. Gentner, and hold exclusive rights and option rights, to certain intellectual property (IP) originating there.

The leadership team's expertise spans from finance and venture capital to medical affairs, from scientific research to clinical drug product development and clinical trial management, having a proven track record as biotech executives. As also stated by Paracchi:

"The secret of our good fortune in the U.S. was a team with enormous experience especially in product development and a science that has 25 years of history that has already been validated on rare diseases and is now stepping into oncology, already having all that backbone of experience coming from treating rare diseases."

They believe in fact that this multi-disciplinary competence, provides a unique blend for the development of innovative gene and cell therapy products, and constitutes a fertile ground for alliances with industrial partners that could help bring new therapies to patients.
The key figures of the company are:

Pierluigi Paracchi (CEO), is an experienced venture capital healthcare investor has accumulated more than 15 years of board experience in Life Sciences companies. Founder and CEO of Quantica SGR, has also co-founded Axòn Capital and Aurora Science. He was also an investor in Eos "Ethical Oncology Science", which was acquired in 2013 in a total deal of $420 million by Clovis Oncology. Pierluigi is also a member of the Assobiotec Steering Committee, the Italian Association for the development of biotechnology.

Luigi Naldini (Chairman of our Executive Scientific Board), is one of the top genetics' experts in the world and a renowned scientist and academic. He is considered the first to develop the Lentivirus

Gene Therapy. For the past 25 years he has pioneered the development and the applications of lentiviral vectors for gene therapy, which have become one of the most widely used tools in biomedical research. Luigi is currently Director of the San Raffaele-Telethon Institute and Full Professor of Histology and Cell and Gene Therapy at the Vita-Salute San Raffaele University School of Medicine in Milan.has authored more than 275 scientific publications.

Richard B. Slansky (Chief Financial Officer) is a senior financial executive with more than 30 years of experience that spans across public and private healthcare and technology companies at various stages of growth, pre-revenue to commercial. Was Chief Financial Officer in various biopharmaceutical, diagnostic and life science companies, in particular former CFO of OncoSec Medical, Biological Dynamics and GenMark Diagnostics. Has raised $500M+ in equity and debt capital in public and private offerings.

Bernhard Gentner (member of Executive Scientific Board) is a physician scientist, serving as Group Leader of the Translational Stem Cell and Leukemia Research Unit at the San Raffaele-Telethon Institute for Gene Therapy in Milan and Staff Hematologist. Bernhard completed his MD studies at the University of Heidelberg, Germany, and his hematology training at San Raffaele Vita-Salute University and has authored more than 30 scientific publications.

Genenta is a very promising company with a complex project that could revolutionize the healthcare industry, thinking about the company's vision, we can only think about the long term; in fact, the company has a long and winding path ahead of it full of unknowns, which it will face however with the ultimate goal clear in mind.

The best way to define Genenta's vision is by asking it to its founder Pierluigi Paracchi, as well as CEO, who holds the helm of the company, in fact during the interview Paracchi declared that:

"The vision is to have an impact on the patient and on the tumor microenvironment. To change the clinical history of these patients and to grow therefore demonstrating that this technology is, as we have seen at the pre-clinical level, extraordinary."

To reach this objective the company can refer to its key strengths that differentiate the company from other competitors by bringing a competitive advantage. As described in the official prospectus the key strengths include: unique and valuable expertise, deep pipeline with broad utility, solid tumors targeting, active and sustained tumor surveillance.

Genenta's project is to develop a novel biologic platform which involves the *ex-vivo* gene transfer of a therapeutic candidate into autologous hematopoietic stem/progenitor cells (HSPCs) to deliver

immunomodulatory molecules directly to the tumor by infiltrating monocytes/macrophages (Tie2 Expressing Monocytes - TEMs). This type of therapy falls under the category of Advanced therapies, technically called ATMPs (Advanced Therapy Medicinal Products), that are those innovative therapies or drugs that differ from more "classical" drugs because they are based on DNA or RNA and cells, offering new opportunities for the diagnosis, prevention, or treatment of genetic diseases and cancers.
Paracchi in the interview explains in a simple way how the technology works:

"We are developing a controlled delivery technology called Temferon. To put it simply we are able to genetically engineer the blood stem cell that is the mother of the immune system so that it expresses white blood cells, a line of cells that are naturally attracted to tumors because they serve the tumor to grow. The scope is to engineer them so that these cells express a specific anti-tumor payload. The advantage is that we are able to avoid systemic toxicity and express the payload that an inflammatory cytokine protein within the tumor microenvironment and not systemically."

More in detail the lead product candidate, Temferon, consists of genetically modified HSPCs which use the platform to deliver interferon-alpha (IFN-α) payload, within the tumor microenvironment. As a result, the immune system can recognize the tumor, respond, and inhibit tumor growth.
The technology is designed to turn TEMs, which normally have an affinity for and travel to tumors, into a "Trojan Horse" to counteract cancer progression and to prevent tumor relapse.

Because Temferon delivers the IFN-α payload directly to the tumor, it should demonstrate clinical activity without the side effect profile of systemic delivery, IFN-α is in fact a well-known therapeutic that was previously used for treatment of various cancers but is currently rarely used due to its systemic toxicity.

In preclinical state, Temferon was used to treat cancer mouse models, both direct and indirect effects were observed. The main target at the moment is the Glioblastoma ("GBM"), a solid tumor affecting the brain, GBM is the most common malignant primary brain tumor accounting for more than half of all central nervous system (CNS) cancers and for which there is a high unmet medical need. The incidence rate is 3.20 per 100,000 persons, this disease is lethal and left untreated, the median survival is 3 months resulting in more than 13,000 deaths per year in the United States as also explained by Paracchi on the interview:

"*Today we are treating a very aggressive tumor the Glioblastoma, which has a life expectancy around 12-14 months and there is no treatment except palliative. We have a technology that from our point of view can be revolutionary and can be a "first in class", because it could change the tumor microenvironment so that it can rebalance itself, to be instead of pro-tumor, against the tumor. And this*

technology could be used in various tumor indications, after that we would like to expand into others tumors treatments."

Since they are developing a platform that is not target dependent, this approach may be used across a large variety of cancers. The Company intends in fact to continue its clinical trials in Europe and possibly initiate a clinical trial in the United States to study Temferon in other tumors,
The current pipeline, with clinical and preclinical stage programs, is summarized in **Figure 10** below:

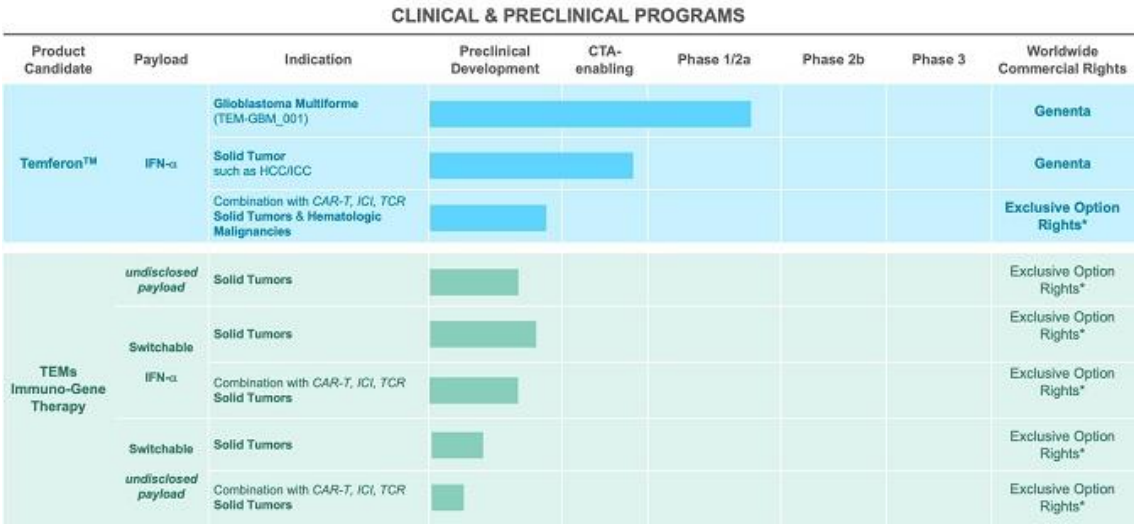

Figure 10 – Clinical and Preclinical Stage Program. Source: Genenta Prospectus 2021.

The company believes that the growing results of early clinical data evidencing the potential of the gene therapy approach, coupled with the founders' expertise in the development, manufacturing and commercialization of gene and cell therapies, positions Genenta well to provide potentially transformative therapies through a single administration to patients suffering from a broad range of cancers.
Paracchi explains that in the last years they have collected important and promising data in the pre-clinical phase that thanks to new rounds of investment have been able to pass this phase starting to treat patients, as explained more in detail in the interview:

"We have moved from the pre-clinical phase to the clinical phase by treating patients for a while now, we are doing it in dose escalation. We will complete enrollment of these patients for phase one and two between the end of this year and the beginning of next year. Then we go into expansion, meaning find the right dose, hopefully as high as possible. In this study we will go into expansion of that dose, so today we do three patients per dose going up. At that point the found dose that is the decisive one, we

take it and expand it for a much larger number of patients in order to give statistical consistency to the clinical data."

3.2 Genenta's Financial Analysis.

At the moment Genenta doesn't have a product approved for the commercial sale, so it hasn't generated any revenue and have incurred losses each year. The losses for 2019 and 2020 were respectively approximately 4.6€ million and 5.6€ million. For the year 2021 instead the company reported 9,1€ million in losses. In total as June 30, 2021, the company has accumulated a deficit of approximately (25.5) € million. The operating losses resulted from costs related to general and administrative costs, research and development, including the pre- and non-clinical development of the gene therapy leading product, "Temferon".

In 2020, the company's cash and cash equivalents were approximately €15.5 million, decreasing the next year to €10.6 million and its short term assets (€38.8M) exceed its short term liabilities (€1.1M). If the use of cash continues at the historical rates the company expects to need significant additional financing, which may seek through a combination of private and public equity offerings, debt financings and collaboration, strategic alliance and licensing arrangements.

Since Genenta doesn't generate revenue, it doesn't have indicators for comparisons, only according to its Price-To-Book Ratio (3.6x) compared to the US Biotech industry average (1.5x) the company is overvalued.

As a result of the Public Offering, approximately € 29 million was received, net of listing expenses of approximately € 3,9 million incurred during the 2021 financial year.

Since 2014 when the company was established, it completed various rounds of investments represented in **Figure 11**.

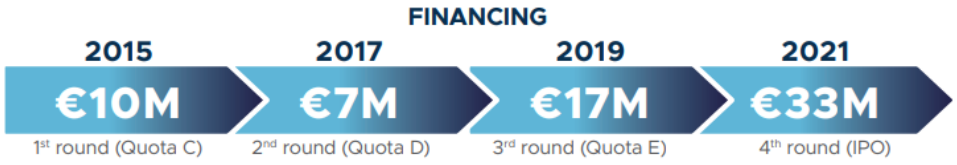

Figure 11 – Financing Rounds 2015-2021. Source: Genenta Fact Sheet 2021.

Starting from 2015 the company had concluded a €6.2 million round in January, thanks to a group of private investors raised by Banca Esperia (Mediolanum Group and Mediobanca) from among its private

banking clients, including FIS Holding, a leading manufacturer of chemicals for the pharmaceutical industry, based on a pre-money valuation of €20 million.

Paracchi explains that: *"In 2015, thanks to Mediobanca, we did the first €10 million funding round. From there, every two years, we did a new round. Over the years we have been supported by many important families in Italian entrepreneurship. I mention for example the Rovati family, founder of Rottapharm. But also Ferragamo, Miroglio, Fumagalli, Ferrari, Bormioli, and top managers or entrepreneurs such as Giuseppe Vita and Matteo Marzotto."*

Then in September 2017 the company had cashed in a €7 million round, led by Italian, British, and Swiss private investors, family offices, and business angels, including, Fidim and Giuseppe Vita, former chairman of the Schering-Plough pharmaceutical group, based on a pre-money valuation of 45 million; Resources that enabled the company to complete the pre-clinical trial.

In September 2019, Genenta had instead announced the closing of a €17.1 million round led by Chinese private equity Qianzhan Investment Management and Fidim, the holding company of the Rovati family, former owner of the pharmaceutical group Rottapharm, participated in the round, based on a pre-money valuation of €70 million.

Notably, the latest round, was in July 2020, when shareholders approved the issuance of new shares totaling €1.5 million, based on a pre-money valuation of €90 million, with lead investor GM Investimenti, the holding company of Giuseppe Miroglio.

The scaleup raised capital from various investors, all for a combined total of €35.1 million. Concluding with the IPO in December 2021.

"The capital raised from the listing is needed from here until the end of 2024 for the expansion of the technology into phase 2." as stated by Paracchi.

Specifically, the company plans to use the net proceeds from this offering, together with the existing cash and cash equivalents, as follows:

- $5.3 million to complete the current Temferon trial, which is expected to enroll its last patient in the second quarter of 2022, and has been designed to establish clinical proof of concept and determine a therapeutic dosage of Temferon that is safe and well tolerated for patients in order to advance the clinical program to Phase 2;
- $0.6 million to support long-term monitoring of the patients in the Temferon trial required by applicable regulations, which is expected to run through 2029;
- $1.0 million to fund preclinical research performed in the laboratories at San Raffaele Hospital. The aims of the research programs include the development of Temferon across a broad range of

cancer indications, second generation switchable Temferon, additional payloads and combination therapies.

- $11.2 million to conduct the clinical Phase 2 synthetic controlled study of Temferon in approximately 30 patients expected to take place from early 2023 to late 2025, with the objectives of safety, tolerability and efficacy of a single dose compared to matched patients in the synthetic arm receiving standard of care. The results of this study could help to develop an adaptive study design for the registration of Temferon in newly cancer diagnosed patients;
- $7.2 million to fund Temferon manufacturing activities for the Phase 2 trial, including the manufacturing, stability and process scalability studies and technology transfer activities.
- The remaining funds for ongoing business development activities, general and administrative expenses, the costs of operating as a public company, working capital, and other general corporate purposes.

3.3 First Italian Company listed on Nasdaq: How and Why.

The listing process began on December 15, 2021 with the ticker symbol "GNTA," and the offering ended on December 17, 2021. The company has closed the initial public offering of 2.4 million American depositary shares (Ads, i.e., a marketable security that represents the securities of a foreign company and allows that company's shares to be traded in the U.S. financial markets) and sold 720,114 shares of common stock reserved for subscription by existing shareholders, raising approximately $36 million. The total number of outstanding shares resulting after the offer is 18,216,858 of which 15,720,114 are ordinary shares and 2,496,744 ADSs.

Figure 12 – Closing bell ceremony of Genenta. Source: IlSole24ore

The company listed with an offer price of 11,5 $ per share, brought Genenta's market capitalization to approximately 200 $ million. Following the IPO, the top management was diluted from 34.49% to 28.47% of the capital and San Raffaele Hospital from 12.64% to 10.47%.
Wanting to look specifically at the company's major shareholders, it is possible to perform an analysis on the type of holding entities: General Public has 59,8%, Individual Insiders has 29,2%, Private Companies 10,4% and Institutions 0,6%.

The main subjects involved in the process are: Roth Capital Partners that was appointed as sole book-running manager of the placement, Maxim Group instead acted as lead manager.
The placement consortium was advised by Goodwin Procter, on the Italian side LCA Studio Legale advised the placement consortium, Loeb & Loeb advised Genenta Science on the U.S. law aspects, the company has relied on Spada & Partners for the Italian law tax aspects of the prospectus. The Bank of New York Mellon, as custodian bank, was assisted by Emmet Marvin & Martin.
The strategic rationale for this big step have different reasons, first it was made with a view to attract international investment, in fact the need to seek fresh capital from the market stems from the need to pursue and implement a sustainable strategy for the development in the industry and leading clinical trials to show the desired results for the authorization of the drug.
According to the CEO of Genenta Science, Pierluigi Paracchi: *"In all high tech investments, both digital and biotech, are very capital intensive. I think as a really competitive tech company, it is difficult to set up and make competitive with investments that are less than 50-100 million. To increase the mass of capital needed to develop the technology, there are the financial markets that have that purpose. So it's a tremendous showcase to attract international capital and to give much more certainty for investors. We chose to be listed in the U.S. market because it is where our competitors are by far concentrated, and as a result banks, analysts, specialized investors are all or largely more in the U.S. than compared to Europe and Asia."*

Since it's complicated for European biotech companies to enter US public markets due to an abundance of local competition they try to land on the Nasdaq or the New York Stock Exchange when the market is high and the IPO window is wide open just to reduce the discount.
The recent phase I/II data of Genenta's lead cancer gene therapy justified the decision to go public, explained also by Paracchi: *"We chose to go there because it is the reference point of capital as far as the technology sector is concerned. We are entering a competent and competitive market, where we are the only Italian biotech but there are six hundred others listed. We are happy that our work has managed to attract such interest in American investors."*

Having won American prominence, now Genenta has already set some goals for the future, first to validate the technology in a phase two and then to find the alliance with some pharmaceutical giant and continue with phase three.

3.4 Results Obtained in the First Quarter (Q1) 2022.

Genenta's initial price, as we can see from the graph below, is 11,50$. By the end of the day, the stock closed at 11$. However, after the company's debut, the global market experienced an important decline affecting the overall high-tech sector and Nasdaq itself. The main causes of this phenomenon are external factors, such as the war between Russia and Ukraine. Moreover, the rising inflation has contributed to this declining trend.

Genenta's stock price in the first quarter (Q1) reached all time low at 5,11$ losing about 55% of its value. After that the stock stabilized in the range of 6-7$.

A comparison of the stock performance can be made to its main benchmark, The Nasdaq Biotech Index that as we said contains the securities of biotechnology companies listed on the NASDAQ, as represented in **Figure 13** in blue the Genenta (GNTA) stock performance and in orange the NBI stock performance.

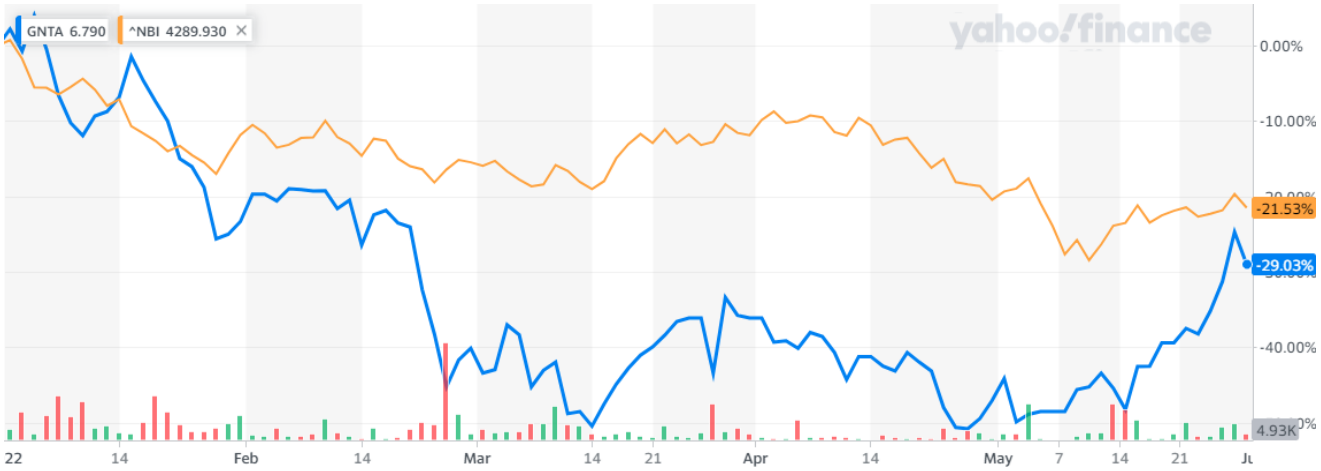

Figure 13 – Comparison of Genenta (GNTA) to NBI 1 Year Performance.

Source: Yahoo Finance

Observing that the company underperformed the market and is still losing about 30% of its initial value so the question is if it is still reasonable to invest in a biotech company like Genenta, considering the potential risks and the possible outcomes.

Genenta is an emerging biotechnology company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it involves important upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or safety standard, receive regulatory approval and become commercially profitable. To invest in a biotech company is crucial to understand the Food and Drug Administration (FDA) approval process. Before a company can sell a drug to the public, the FDA must be convinced that it is safe, a simplified version of the steps a biotech company must take to receive FDA approval:

• Preclinical testing (six months to one year).
• Phase I: testing on patients (one to two years).
• Phase II: wider testing (one to two years).
• Phase III: final phase (two to three years).

If the drug is approved at Phase III, the stock price of a biotech company will usually soar. But the process is still not over! The company then files an FDA application for marketing approval. This can take about one year, after which the company is free to market and sell the drug to the public. But even after all this, there still may be risks; that is, there may be unanticipated side effects. If so, the FDA may require that the drug be taken off the market.

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid and significant technological advancements.

The competition is high since large pharmaceutical and biotechnology companies are pursuing the development of product candidates for the treatment of cancer that may be commercialized in the future. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Potential indirect competitors also include government agencies academic institutions, and public research organizations.

Genenta's competitors may succeed in developing, acquiring or licensing technologies and products that are more effective, more effectively marketed and sold or less costly than any product candidates that may develop, which could render the product candidates noncompetitive and obsolete.

In addition, Genenta depends on license agreements with OSR to permit to use patents and patent applications, as well as to exploit specific OSR know-how. Termination of these rights or the failure to

comply with obligations under these agreements could materially harm the business and prevent from developing or commercializing product candidates.

There are 375 projects of new therapeutics under study in Italy, of which about 131 are in the discovery phase. The interest of national biotech research is mainly oriented toward the development of therapeutic solutions for oncology. Oncological diseases rank second among the major causes of death in 2019 with about 180,000 deaths, right after cardiovascular diseases (about 233,000 deaths).
Despite the Italian Biotech network is not well-known, it represents excellence in the field of advanced therapies, having been one of the first countries to have contributed to the European release of a high number of products on the European market. Some of the competitive advantages are: a solid scientific tradition, primary research institutes, competitive scientists.
There are 199 Italian companies developing human health diagnostic products and services, nearly 30 percent of those in the entire biotechnology sector in Italy. Of these, the vast majority are micro-sized, 65% and focused on oncology projects.

The future of biotechnology is unknown, however, despite all the risks and difficulties, it has the potential to positively change our lives and revolutionize a sector that is constantly growing at an incredible pace.

"The industry is booming, I see biotech today as the internet in 1995 so a revolution, then like all revolutions it can have periods of strong growth and hype and periods of collapse where it seems like the end, but the technology is so stable that it corrects itself a little bit and finds a shape. Gene therapy, gene editing, cell therapies, and advanced therapies will experience volatile times, but they are here to stay for the next 100 years."- Pierluigi Paracchi

CONCLUSION

In conclusion, this paper has shown that the listing process is important from several points of view, this decision for a company involves both financial, governance and reputation perspectives.
It was found that, the operation turns out to be an excellent means of raising project financing, mainly for the biotech sector that investing heavily in R&D is capital intensive.

Coming to the listing, which took place on December 20, 2021, it can be said that the arrival of new capital has enabled the company to implement a strategy that makes possible growth and development of the technology. The analysis of the Genenta Science S.P.A case study demonstrated the advantages that can be gained by a fast growing company entering in a new important market, the listing process became necessary in order to be able to compete globally, giving also the opportunity to broaden the pool of investors, in the national and international context. Although the stock has underperformed the market, the company could have a long and bright future ahead.

The biotech market is becoming increasingly competitive and global and serves as a driver for many other related industries. Because of this, companies operating within it face increasingly fierce competition by trying to get funds for they innovative projects and treatments.
Indeed, it is evident that among all the negative events and misfortune brought by this terrible pandemic, there are undoubtedly new opportunities that cannot be ignored, by placing a spotlight on the healthcare sector it is more clear that biotechnologies will play an important role in the future.

In conclusion, we can say that the listing transaction has undoubtedly provided a strong momentum to Genenta's future and that consequently represents a fundamental step in getting closer to revolutionize the market and the world.

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APPENDIX

PERSONAL INTERVIEW TO PIERLUIGI PARACCHI, CEO OF GENENTA

1. When, how and why was Genenta born?

Genenta was born in 2014 as a spin-off of San Raffaele, when I was doing venture capital and I met this professor who is Luigi Naldini, who is the director of the San Raffaele Telethon Institute for Gene Therapy. After the 2013 when I sold the venture capital company Eos "Etica Oncology Science." an Italian biotech company in the oncology sector, we sold it for $420 million to a Nasdaq-listed company. So I was in very positive hype, regarding the exit, the biotech and oncology sector and when I crossed paths with him I decided to leave the VC company, by putting together my previous experience working for an international venture fund, with the very strong science that he had we decided to launch this venture. Together with San Raffaele and another scientist we went looking for capital.

2. What is your flagship product, how does it work and how are you developing it?

We are developing a controlled delivery technology called Temferon. So we are able to genetically engineer the blood stem cell that it is mother of the immune system so that it expresses white blood cells, a line of cells that are naturally attracted to tumors because they serve the tumor to grow. The scope is to engineer them so that these cells express a specific anti-tumor payload. The advantage is that we are able to avoid systemic toxicity and express the payload that an inflammatory cytokine protein within the tumor microenvironment and not systemically.

I noticed that you have passed the pre-clinical phase and now you are on phase I/ II. What are the next steps?

We have moved from the pre-clinical phase to the clinical phase by treating patients for a while now, we are doing it in dose escalation. We will complete enrollment of these patients for phase one and two between the end of this year and the beginning of next year. Then we go into expansion, meaning find the right dose, hopefully as high as possible. In this study we will go into expansion of that dose, so today we do three patients per dose going up. At that point the found dose that is the decisive one, we take it and expand it for a much larger number of patients in order to give statistical consistency to the clinical data. The capital raised from the listing is needed from here until the end of 2024 just for phase 2, so for the expansion of the technology into phase 2.

As far as approval of a product from the FDA on average it can take 5 years, in fact you have to go for various steps, looking at feasibility, safety, and that there is no toxicity. You have to go and see biological activity, efficacy, doing it always progressively with a larger number of patients until you have certainty. Clearly the time to authorization also depends on the robustness of the data, if you have very convergent data, very clear so, for example, if out of 50 patients in the 40 who respond the timeframe is much faster, and if out of 50 patients on average you have an improvement in the standard of care that manages to demonstrate after a year or two it's clear that you have to progressively have more studies that support.

3. What is Genenta's mission and vision?

We want to have impact on patients. Today we are treating a very aggressive tumor the Glioblastoma, which has a life expectancy around 12-14 months and there is no treatment except palliative. We have a technology that from our point of view can be revolutionary and can be a “first in class”, because it could change the tumor microenvironment so that it can rebalance itself, to be instead of pro-tumor, against the tumor. And this technology could be used in various tumor indications, after that we would like to expand into others tumors treatments.
So the vision is to have an impact on the patient and on the tumor microenvironment. To change the clinical history of these patients and to grow therefore demonstrating that this technology is, as we have seen at the pre-clinical level, extraordinary.

4. What are the strategic motivations for the listing? Why the US and Nasdaq in particular?

In all high tech investments, both digital and biotech, are very capital intensive. I think as a really competitive tech company, it is difficult to set up and make competitive with investments that are less than 50-100 million. To increase the mass of capital needed to develop the technology, there are the financial markets that have that purpose. So it's a tremendous showcase to attract international capital and to give much more certainty for investors. In private investment, in fact, an investor invests in a private company and hope that after X years something happens, if it doesn't happen remains a prisoner of the company. Whereas in a public company it is true that the stock can go up or down, however the investor can in any moment to liquidate the position. So by lowering the liquidity barrier of the initiative, you manage to broaden the amount of investors it can bring in. This was mainly the strategic choice. We chose to be listed in the U.S. because our competitors are by far concentrated in the U.S., and as a result banks, analysts, specialized investors are all or largely more in the U.S. than compared to Europe and

Asia. It's a very competent, very competitive market. If you have the results that go in the right direction of science, you can be rewarded in an extraordinary way. Europe is chasing a market that is growing, but unfortunately is less sophisticated. Asia is coming up in an important way, although access for capital is a bit more complicated, especially in China, where it is almost impossible today. So our choice was in the United States, where moreover we have an office in New York since 2017, our CMO is American, now our CFO, the head of development and part of the board are American.
We listed on 2021, since 2017 we had an office there. I spent a lot of time in the United States and a good part of it was American. Today we are the only Italian company listed on Nasdaq, Genzium that listed on the American exchange and then went to NASDAQ.

4. **The biotech industry is competitive and risky, what do you think are the ingredients of Genenta's success?**

It's a combination of science, entrepreneurship, you must have a very solid science built up over years with results that start to validate your technology, the other key elements are the entrepreneurial side and the team and credibility. Many make the investment because they believe in the team because maybe the see the scientific part as a gamble, others more technical people bet on both. The secret of our good fortune in the U.S. was a team with enormous experience especially in product development and a science that has 25 years of history that has already been validated on rare diseases and is now stepping into oncology, already having all that backbone of experience coming from treating rare diseases.

5. **How difficult and long was the listing process?**

The process is very articulated especially for a non-American company, usually the process can take 6-9 months to complete, obviously many things can happen so it's easy to have a delay coming even to a 1 year. It is surely a very active year and an extraordinary commitment for the team because you have to prepare the company to be listed, you have to adapt to the standard of the American SEC, the bar is very high. It is in fact the most complex, structured and regulated market in the world. The preparation also involves the part of financials, the dealing with banks and with lawyers.

6. **Genenta is the only Italian company being listed in the Nasdaq market, do you remember any anecdote about this listing venture or some details that struck you.**

One thing that struck me that I took it for granted, is that at the time of the listing we would go through the ceremony at Nasdaq ringing the bell, an iconic moment. I find out during the process, nearing the IPO, that Nasdaq has a problem, the number of IPOs is so high that it was almost impossible to find free slots for the ceremony. There were more IPOs than slots, for me it was a dramatic disappointment because as an economics graduate it was the realization of a dream to go to Wall Street and ring the bell. So we had to explain to Nasdaq that we are the only Italian company listed and that the Italian ambassador or consul in New York would come to the ceremony. At the end the consul in New York came and convinced NASDAQ to give us a slot very close to the IPO, we listed on the 15th and on the 20th we were in New York doing the closing bell ceremony which was an extraordinary milestone.

7. **Has Covid changed the biotechnology market and business? If so, in what ways?**

Covid among all the negative things, it popularized the biotech industry, before the jargon of our industry was too complex, people didn't understand. Post Covid we are all more or less confident in talking about trials, virologists, mRNA vaccines, thus popularizing a culture that used to be super niche and very tech. This has made our story-telling much easier. Today it is easier to tell about a company developing a cancer therapy by working on DNA, the world that 2 years ago would have looked at you as an alien now has the base to understand what you are telling, and I consider this revolutionary.

The industry is booming, I see biotech today as the internet in 1995 so a revolution, then like all revolutions it can have periods of strong growth and hype and periods of collapse where it seems like the end but the technology is so stable that it corrects itself a little bit and finds a shape. Gene therapy, gene editing, cell therapies, advanced therapies will experience volatile times but they are here to stay for the next 100 years.