

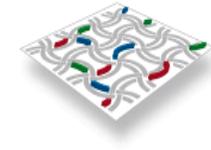
THE BIOTECH SECTOR IN
ITALY AND LOMBARDY



PROMOS
Internazionalizzazione
e marketing territoriale



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LOMBARDY**

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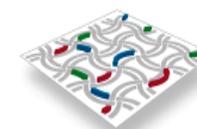


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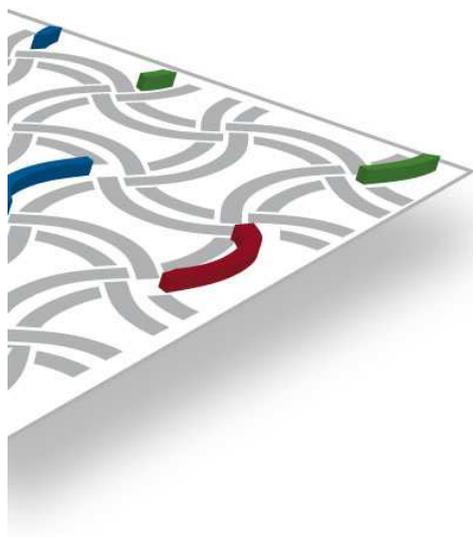


**5. ITALY AND LOMBARDY TODAY: INCENTIVES AND
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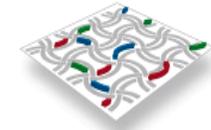


**INVEST IN
LOMBARDY**

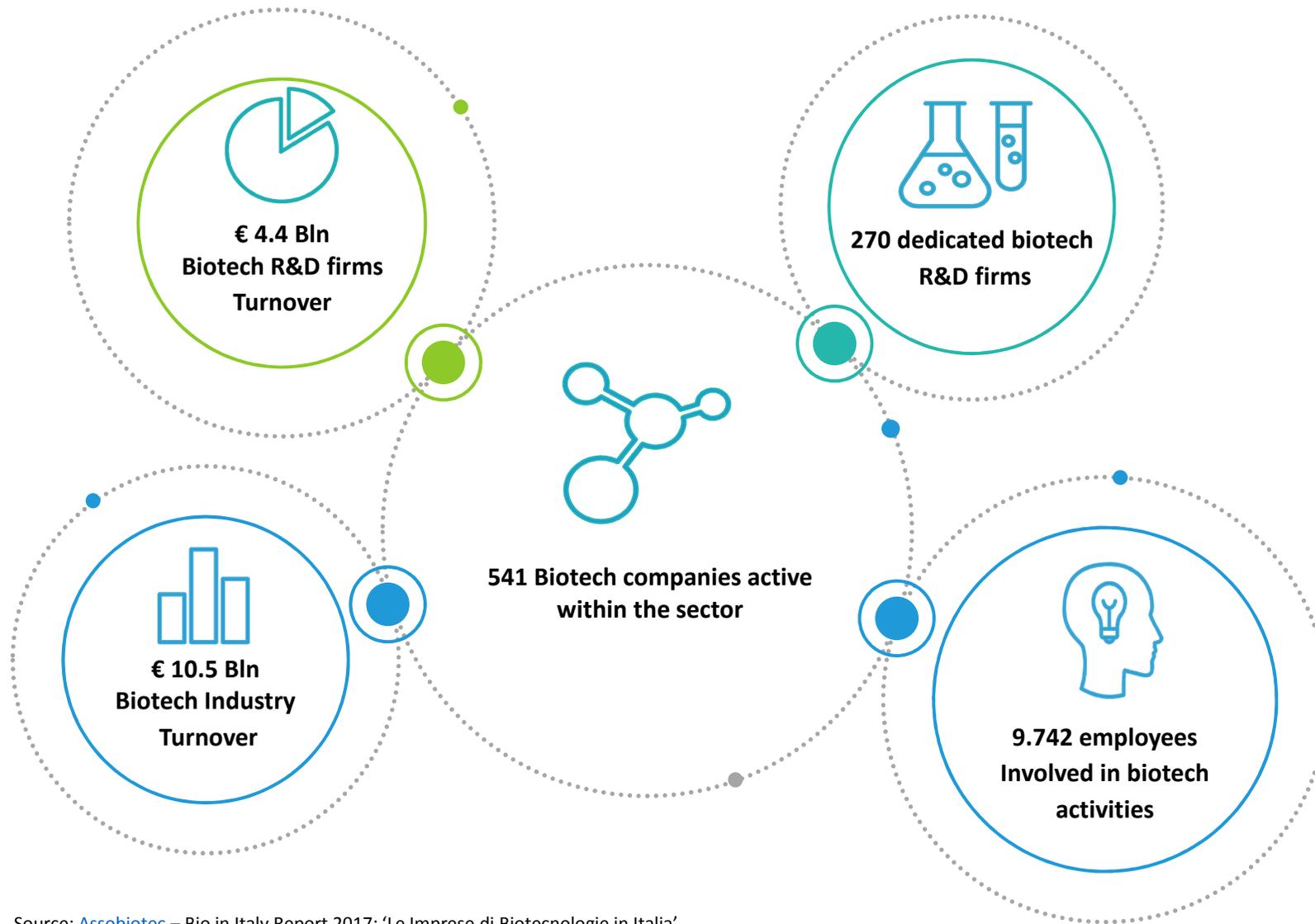


THE BIOTECH SECTOR IN ITALY

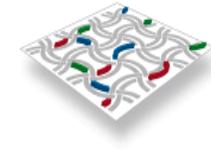
THE BIOTECH SECTOR IN ITALY: KEY FIGURES



**INVEST IN
LOMBARDY**

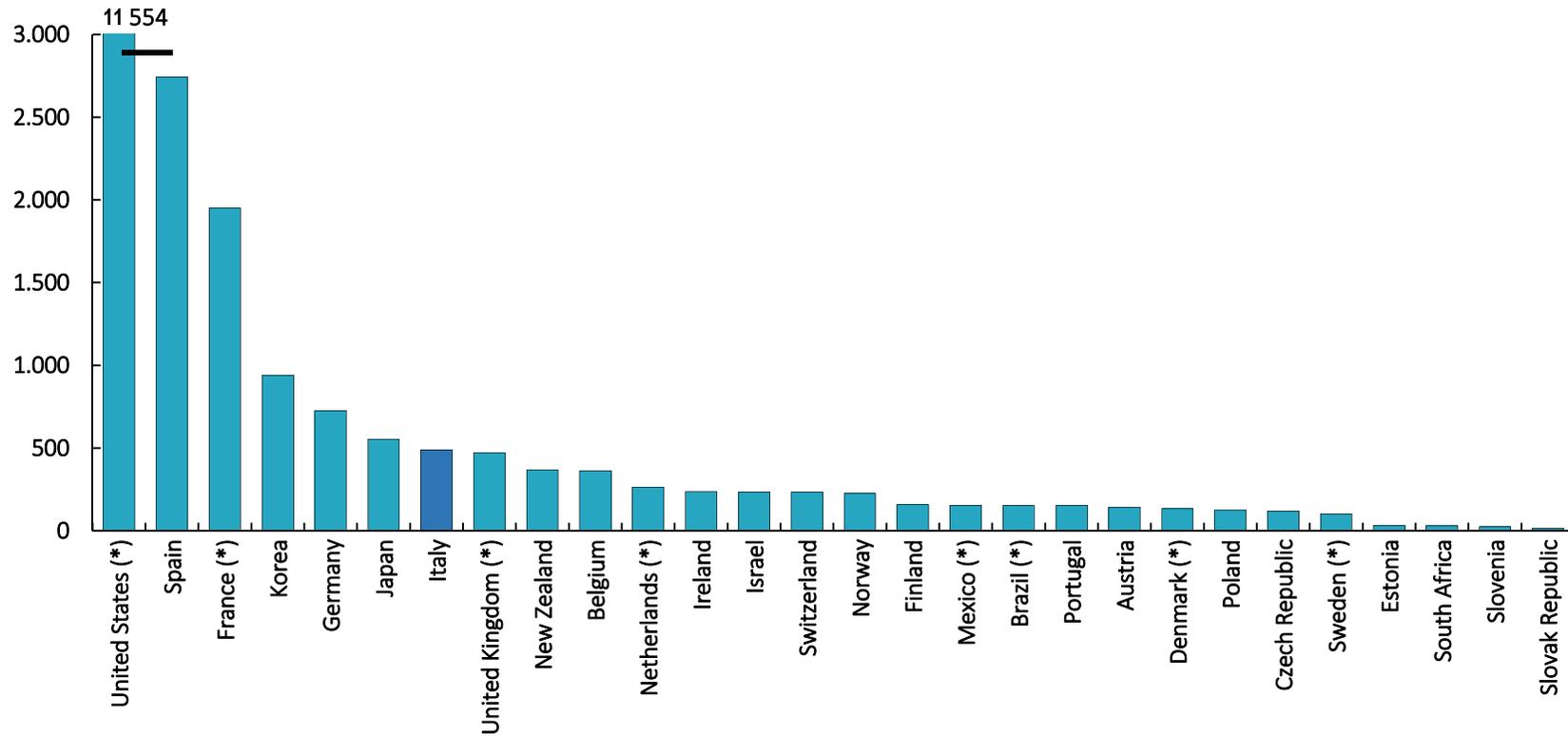


THE BIOTECH SECTOR IN ITALY: FIRMS

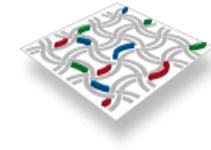


INVEST IN
LOMBARDY

The Italian Biotech Industry is competitive Worldwide: we are the **7th global power** in terms of number of firms active in the biotech sectors

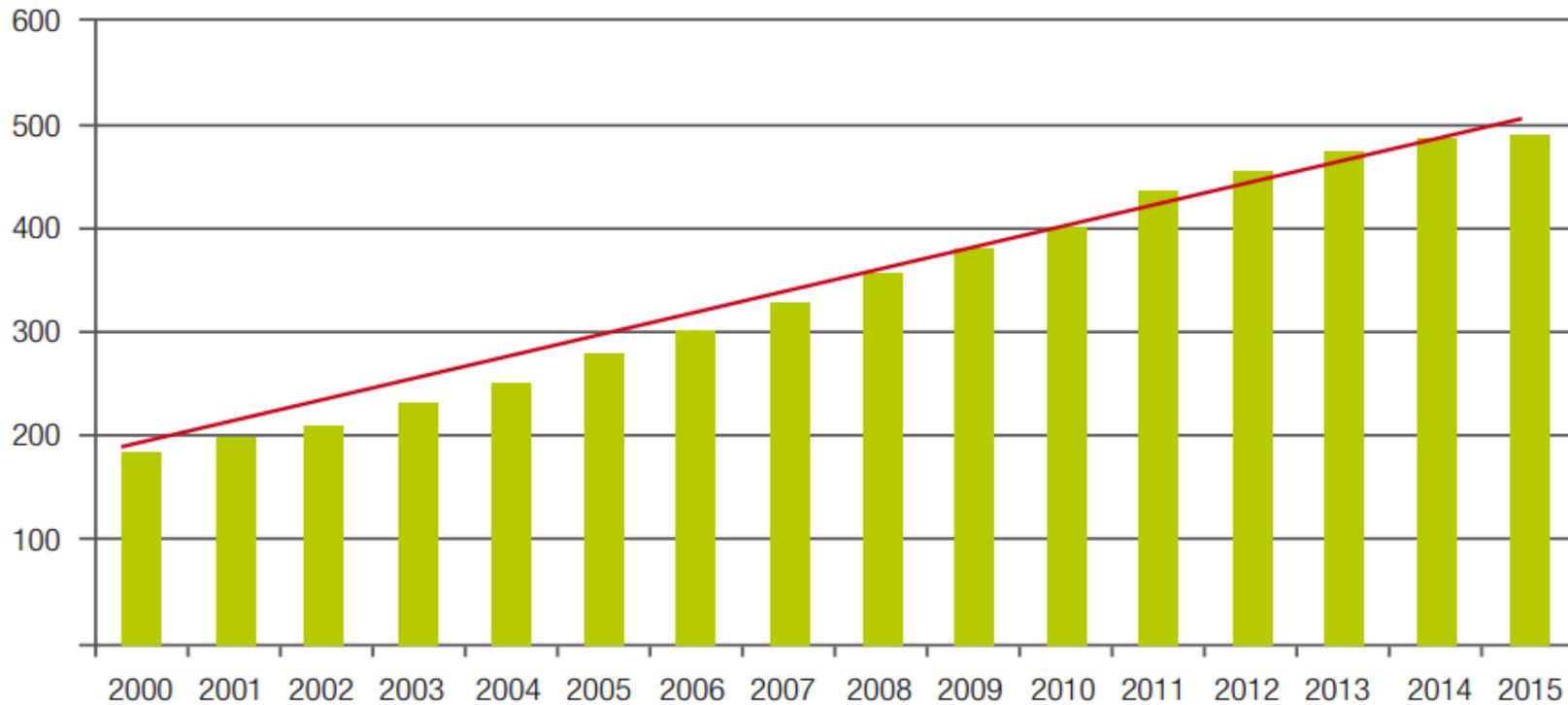


THE BIOTECH SECTOR IN ITALY: GROWTH

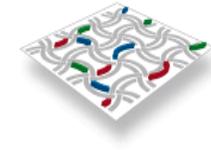


INVEST IN
LOMBARDY

The Italian Biotech Industry **has grown spectacularly** in the last 15 years: the number of R&D firms has **more than doubled**

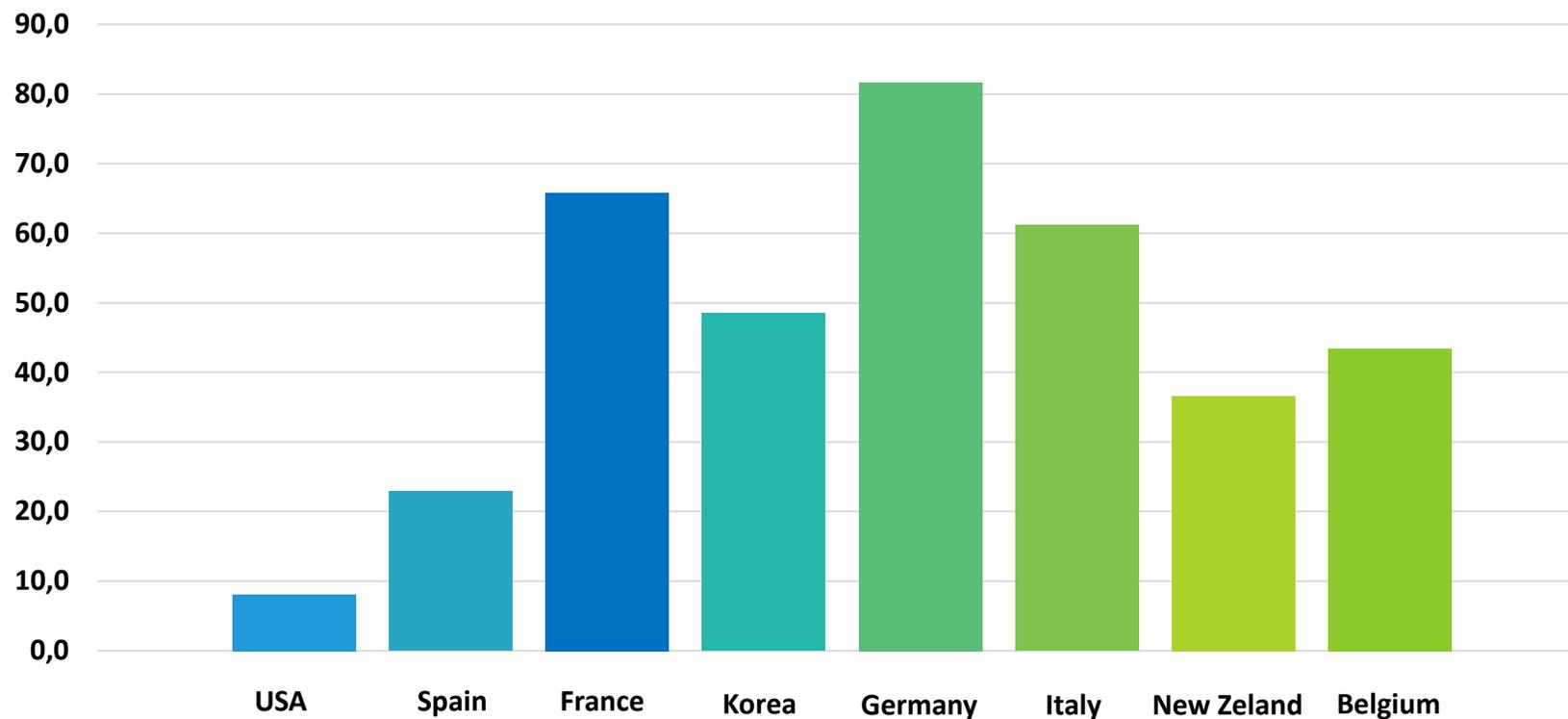


THE BIOTECH SECTOR IN ITALY: R&D FIRMS



INVEST IN
LOMBARDY

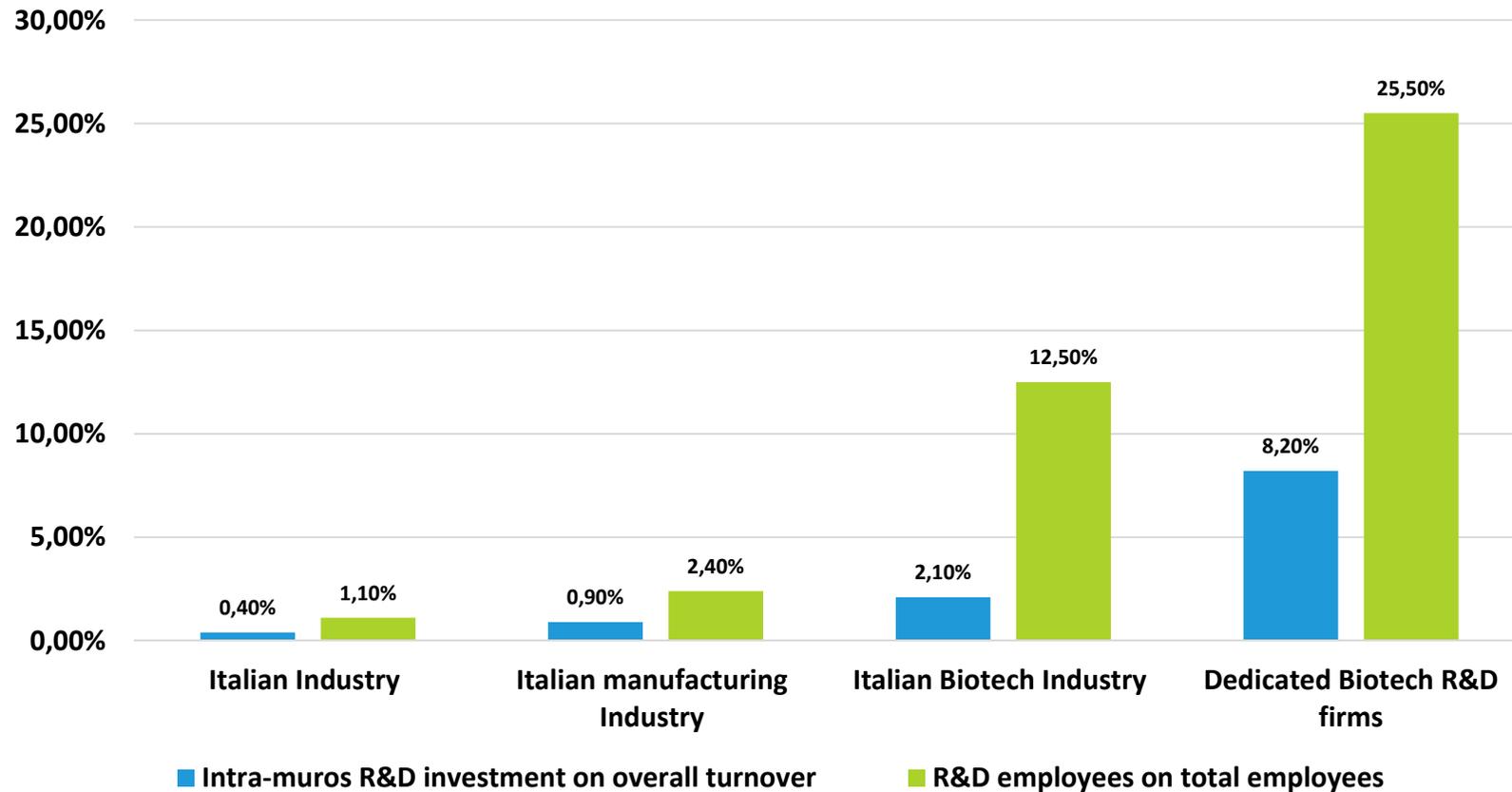
More than **60%** of the Italian Biotech Industry is made up by **Dedicated Biotechnology firms** (firms that devote at least 75% of activities on Biotech). Only Germany and France have a higher percentage out of the 8 top global producers



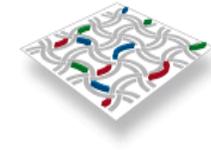
THE BIOTECH SECTOR IN ITALY: A RESEARCH INTENSIVE INDUSTRY



The Italian Biotech Industry is **research-intensive** compared to the whole industrial sector

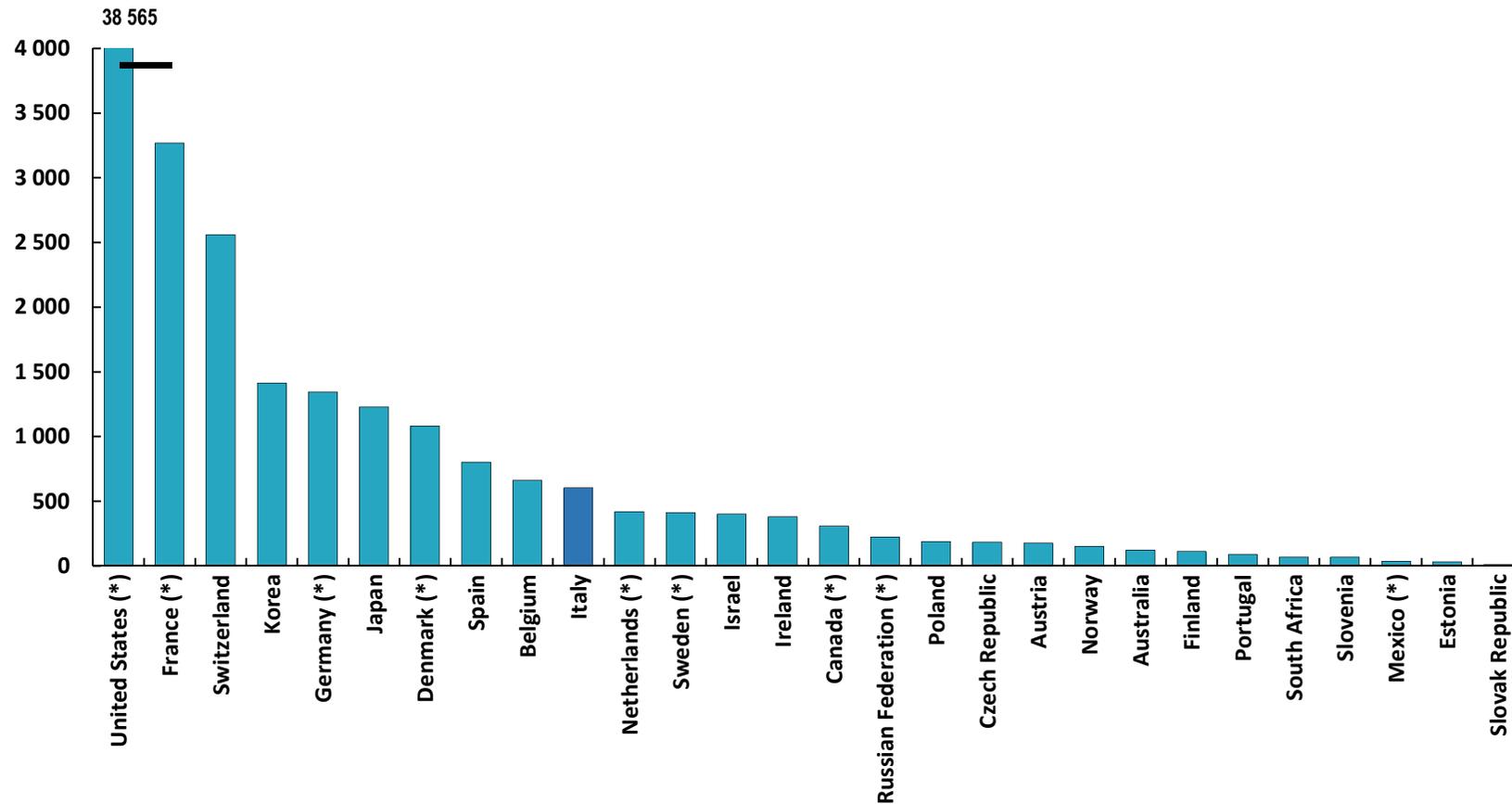


THE BIOTECH SECTOR IN ITALY: R&D EXPENDITURES

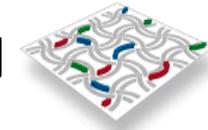


INVEST IN
LOMBARDY

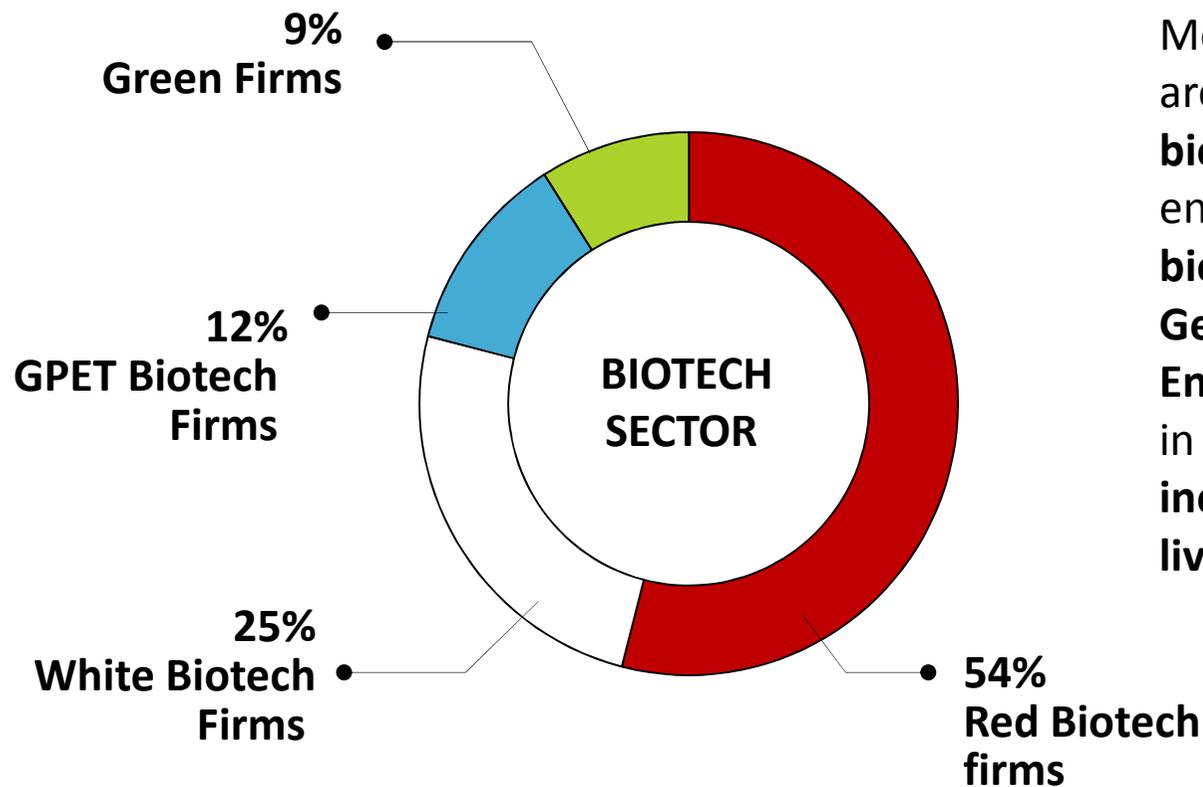
Italy is a **top ten global investor** for R&D Biotechnology expenditures (Million USD PPP)



THE BIOTECH SECTOR IN ITALY: SECTOR COMPOSITION



INVEST IN
LOMBARDY

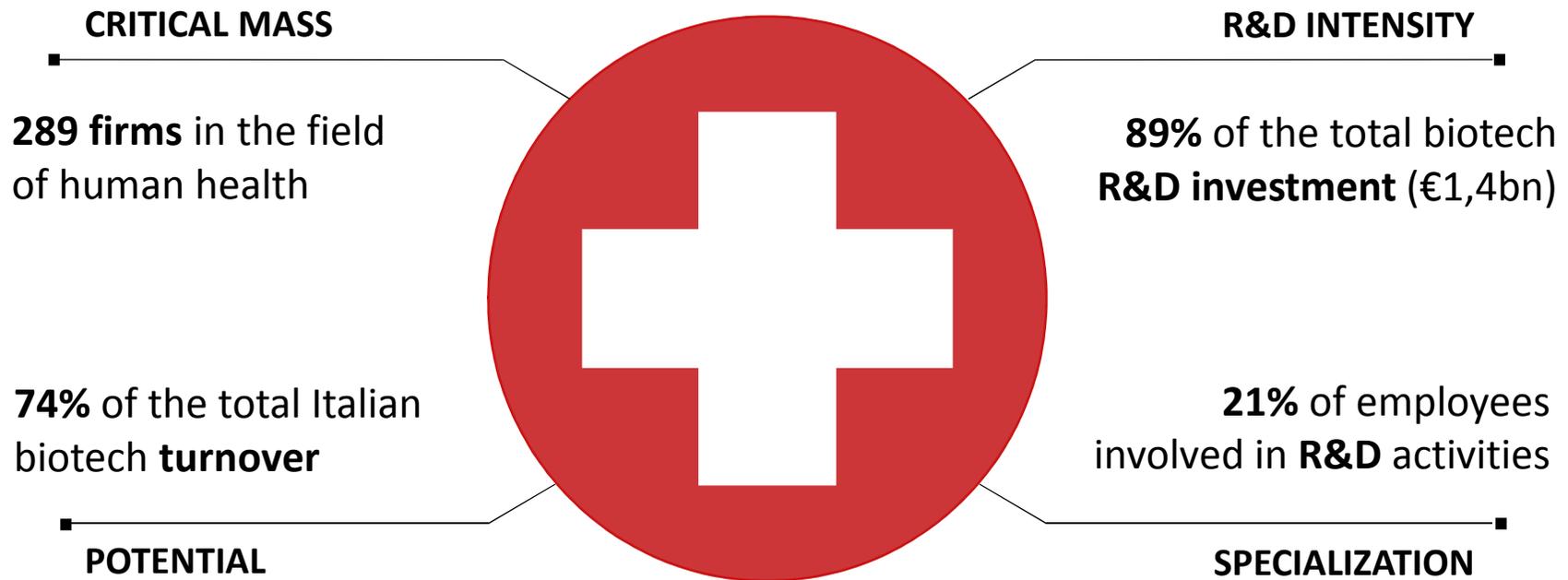


Most of the Italian biotech firms are active in **healthcare biotechnology (54%)**. Others are engaged in **industrial biotechnology (25%)**, in **GPET - Genomics, Proteomics and Enabling Technologies (12%)** and in **Green biotechnology, including agriculture and livestock (9%)**.

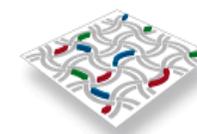
FOCUS: THE ITALIAN RED BIOTECH



- The **Red Biotech** subsector is the **spearhead** of the Italian bioeconomy



THE ITALIAN RED BIOTECH, A GLOBAL EXCELLENCE



INVEST IN
LOMBARDY

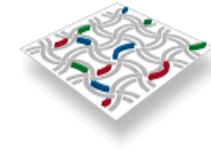
With its groundbreaking Advanced Therapies, Italy is a pioneer and a global leader in the Red Biotech Subsector

- **1° country in terms of n. of Advanced Therapy products** authorized by the EU (3 out of 5)
 - Developer of the **1° approved stem cell-based drug**
 - Developer of the **1° approved gene therapy** as a result of a PPP

	Marketing Authorization	Product	Company		Therapeutic area
1	2016	Strimvelis	GSK- (Telethon)		Severe Combined Immunodeficiency
2	2016	Zalmoxis	MolMed		GVH Disease Hematopoietic Stem Cell Transplantation
3	2015	Holoclax	Chiesi		Corneal Diseases, Stem cell transplantation
4	2015	Imlygic	Amgen		Unresectable metastatic melanoma
5	2012	Glybera	UniQure		Hyperlipoproteinemia

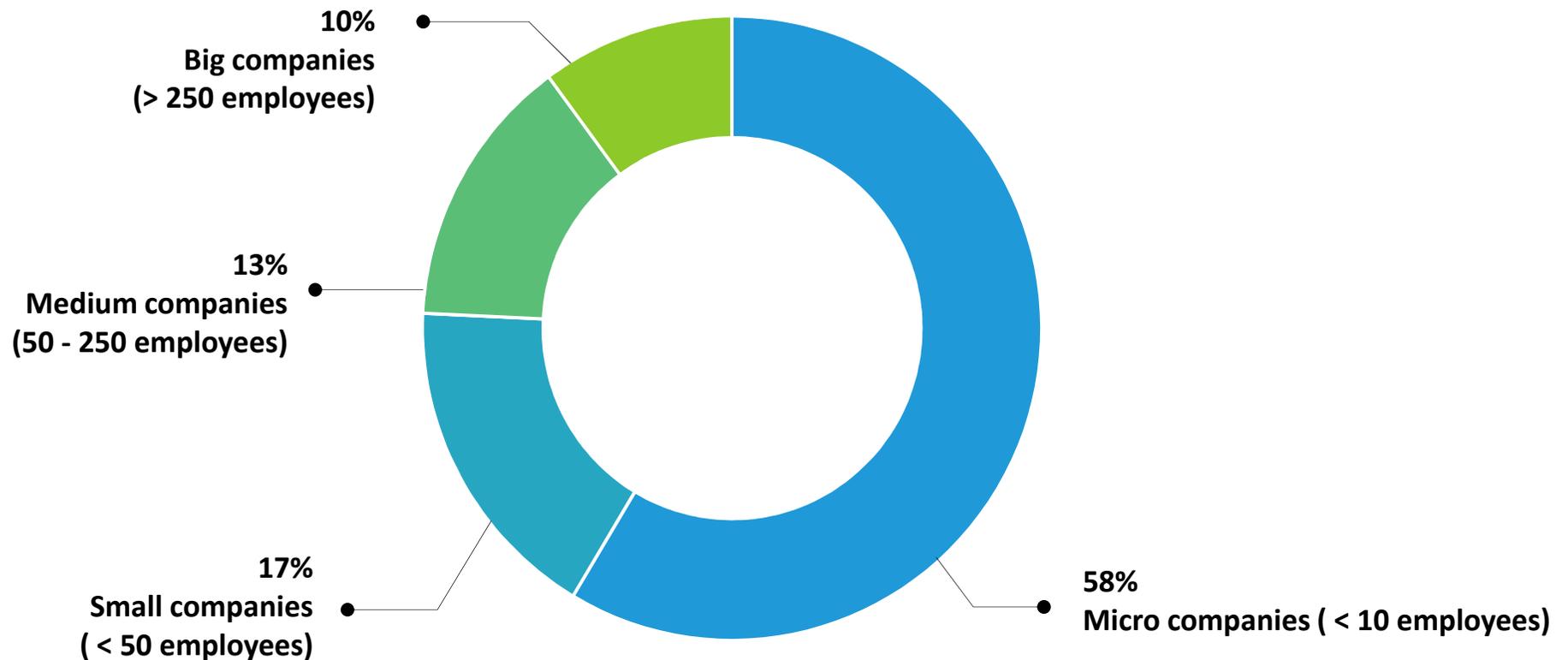
Strimvelis and Zalmoxis are **the only two Advanced Therapies** based on genetically modified cells that have been **filed for a Marketing Authorization at the European Medicines Agency (EMA)**. Both of them are **Made in Lombardy**

THE BIOTECH SECTOR IN ITALY: FIRMS SIZE

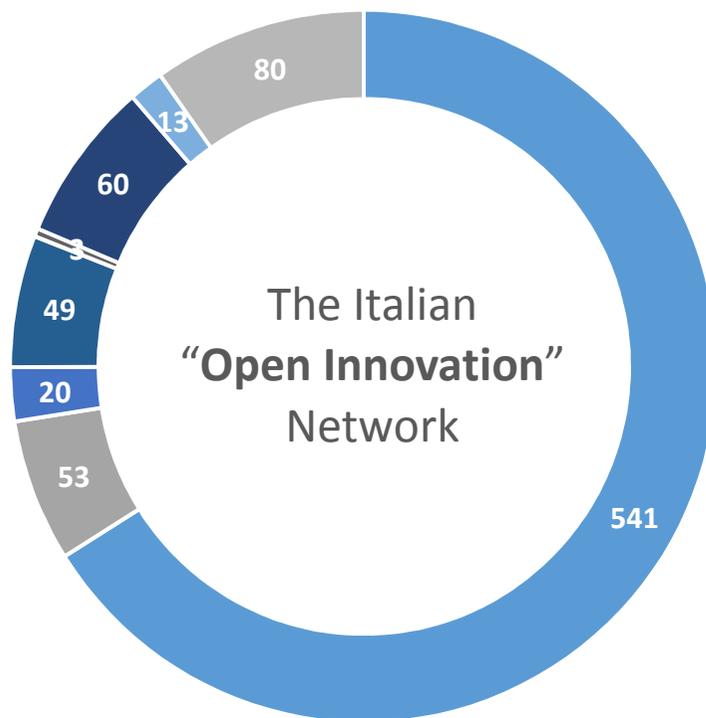
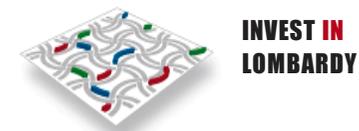


INVEST IN
LOMBARDY

The Italian Biotech Sector is dominated by **micro/small companies**, in particular within the GPET sector . Almost one in two micro-sized company is an **academic spin-off**



THE “OPEN INNOVATION” CONTEXT



- The **ultimate source of competitiveness** for the Italian Biotech sector is the complex **excellence network** of companies, SMEs, startups and non-entrepreneurial players that combine **public, academic and industrial research** throughout an extremely efficient pipeline
- This model has set up a **new standard for cooperative R&D**, where the key word is ***Open Innovation***

■ Firms

■ Technological Innovation Poles

■ Major Public Entities

■ Zooprohylactic Institutes

■ Universities

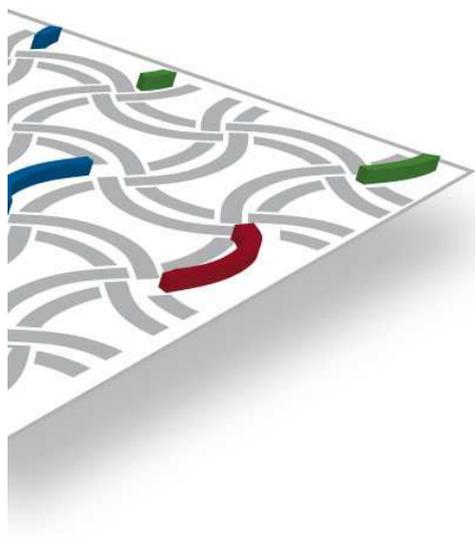
■ Institutes for Research, Hospitalization and Healthcare (IRCCS)

■ Local Departments

■ Foundations, Consortia and Research Centres



**INVEST IN
LOMBARDY**



LOMBARDY: A LAND OF OPPORTUNITIES

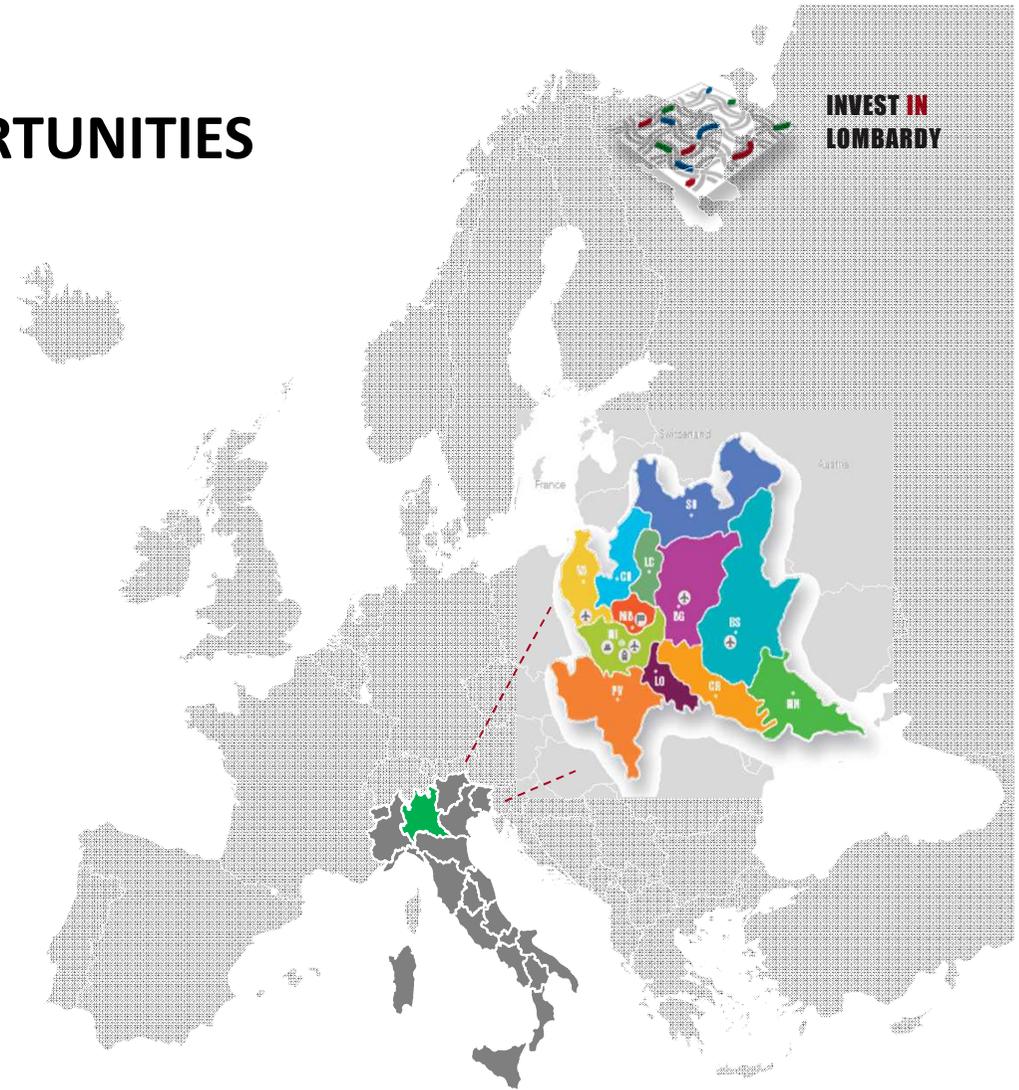
LOMBARDY: A LAND OF OPPORTUNITIES

Lombardy is a land alive with opportunities. Italy's wealthiest region, it generates **22% of national GDP**, higher than Austria, Denmark, Finland, Ireland and Portugal.

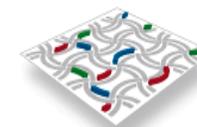
With more than **6.389 foreign invested companies**, Lombardy is an important market for investors able to absorb **60% of FDI coming to Italy**.

Out of 100 top **multinationals** that have invested in Italy, 92 are **housed in Lombardy**.

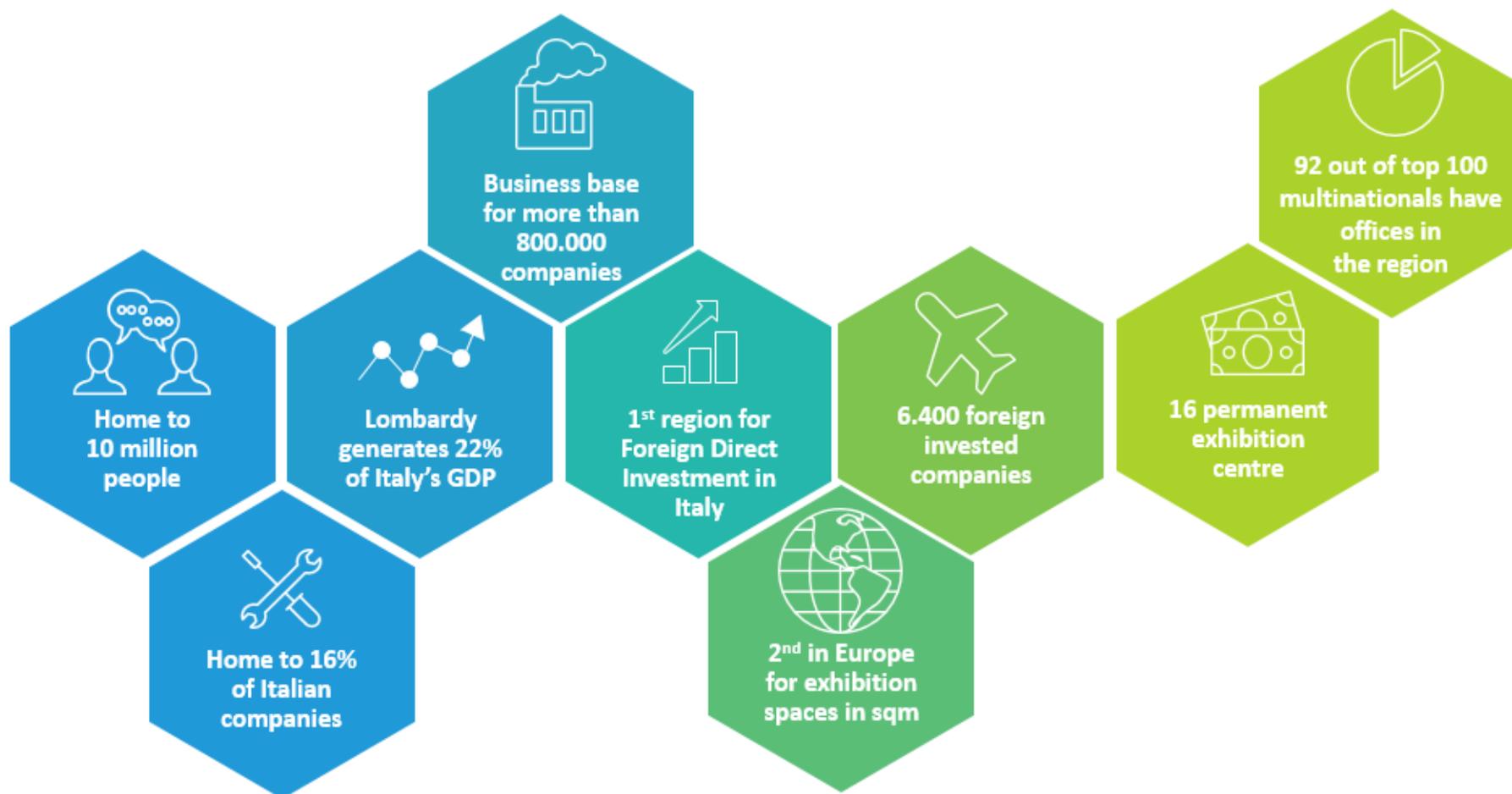
Milan is an **ultimate hub for innovative sectors**, life sciences in particular, and a **serious candidate** to host the next **EMA - European Medicines Agency** - headquarters in the **Brexit scenario**.



LOMBARDY: A DYNAMIC AND PRODUCTIVE REGION

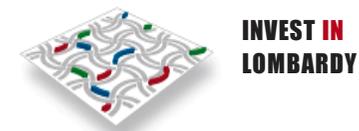


**INVEST IN
LOMBARDY**



p. 17 Source: Why Invest in Milan by JLL; Booklet Italy, Lombardy and Milan by Assolombarda; Research Unit of Milan Chamber of Commerce

LOMBARDY: AN INNOVATIVE REGION



Lombardy leads the way in **innovation and development**: **6** Sciences and Technology Parks, **182** innovative business, **11** National Research Councils and **267** in-house research Institutes

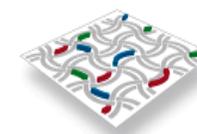
500 research and development centres

6 science and technology parks

10 science and technology clusters

More than a third of the Italian patents recognized by the EU are registered in Lombardy

LOMBARDY: AN INTERNATIONAL HUB

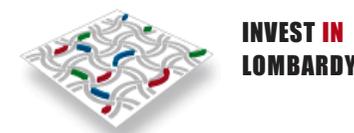


**INVEST IN
LOMBARDY**

Lombardy is an **international hub** and is one of the **top regions** in Europe for **hard** and **soft infrastructures**.



LOMBARDY: LEADING THE WAY IN EDUCATION



12
UNIVERSITIES
within the Lombardy Region, 8 within Milan with more than 250.000 students enrolled



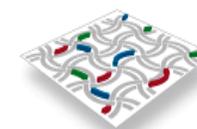
10%
POPULATION
Milan universities represent 10% of Italian university population



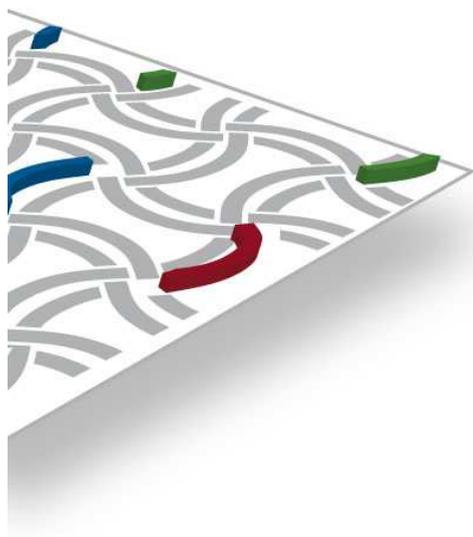
17%
INTERNATIONALS
Almost 1 in 5 international students in Italy are enrolled in Milan universities



28%
SCIENTIFIC PUBLICATIONS
Lombardy produces knowledge: almost 1 in 3 high- impact scientific publications produced in Italy come from the region

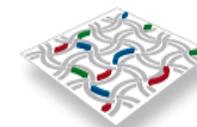


**INVEST IN
LOMBARDY**

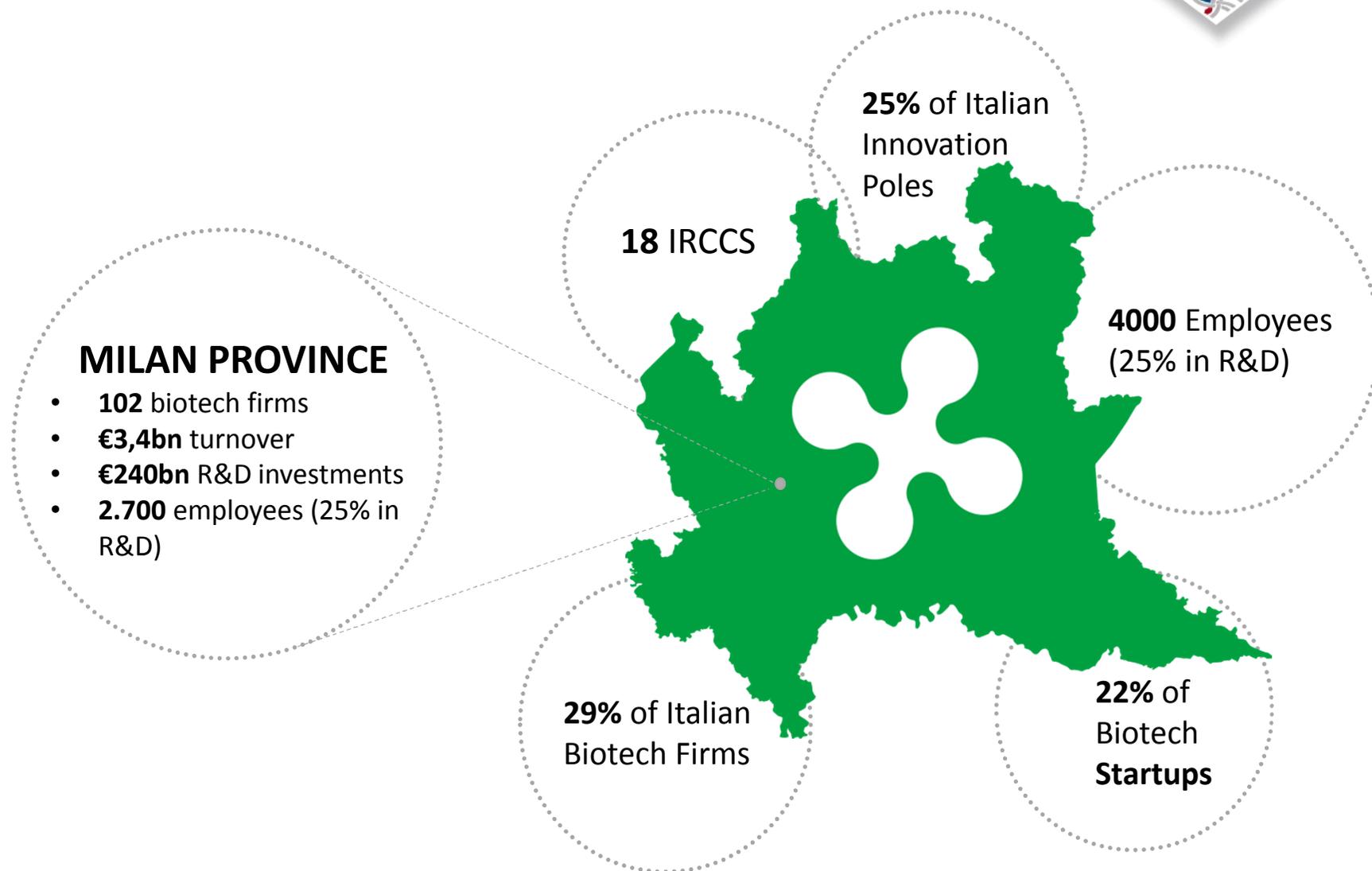


LOMBARDY: BIOTECH FACTS AND FIGURES

THE BIOTECH SECTOR IN LOMBARDY: OVERVIEW



INVEST IN
LOMBARDY



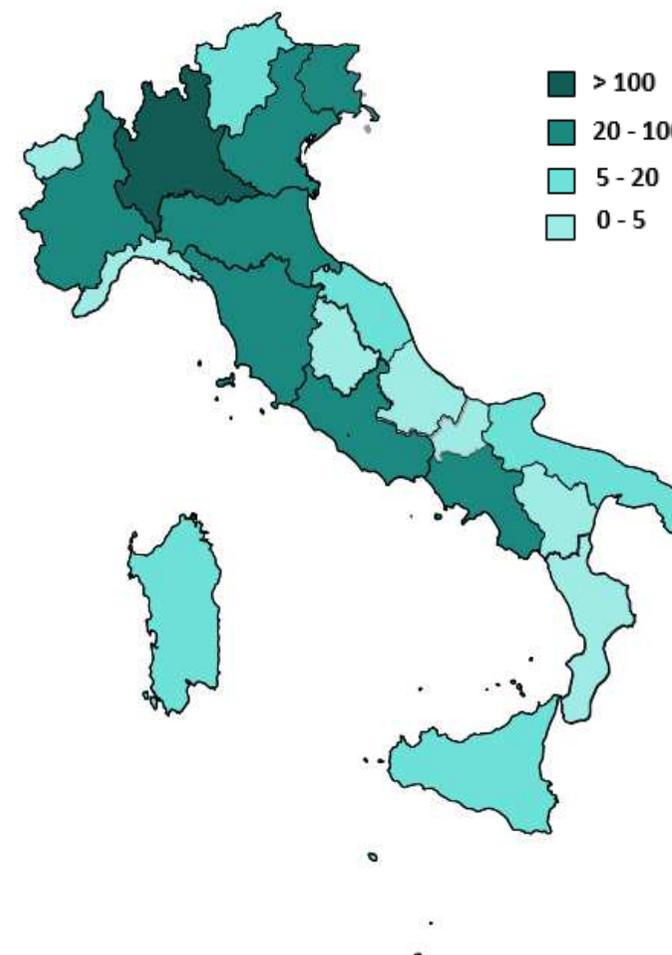
THE BIOTECH SECTOR IN LOMBARDY: FIRMS



**INVEST IN
LOMBARDY**

Lombardy is where the Italian Biotech Industry excels: **29% of firms are located within the region**

Italian Regions	Firms	
	Number	Percentage
Lombardy	155	28,7%
Emilia – Romagna	54	10,0%
Lazio	54	10,0%
Piedmont	53	9,8%
Veneto	41	7,6%
Tuscany	40	7,4%
Friuli - Venezia Giulia	29	5,4%
Campania	27	5,0%
Sicily	15	2,8%
Apulia	14	2,6%
Trentino - Alto Adige	13	2,4%
Sardinia	13	2,4%
Marche	11	2,0%
Liguria	7	1,3%
Other Italian Regions	15	2,8%
Total	541	100%



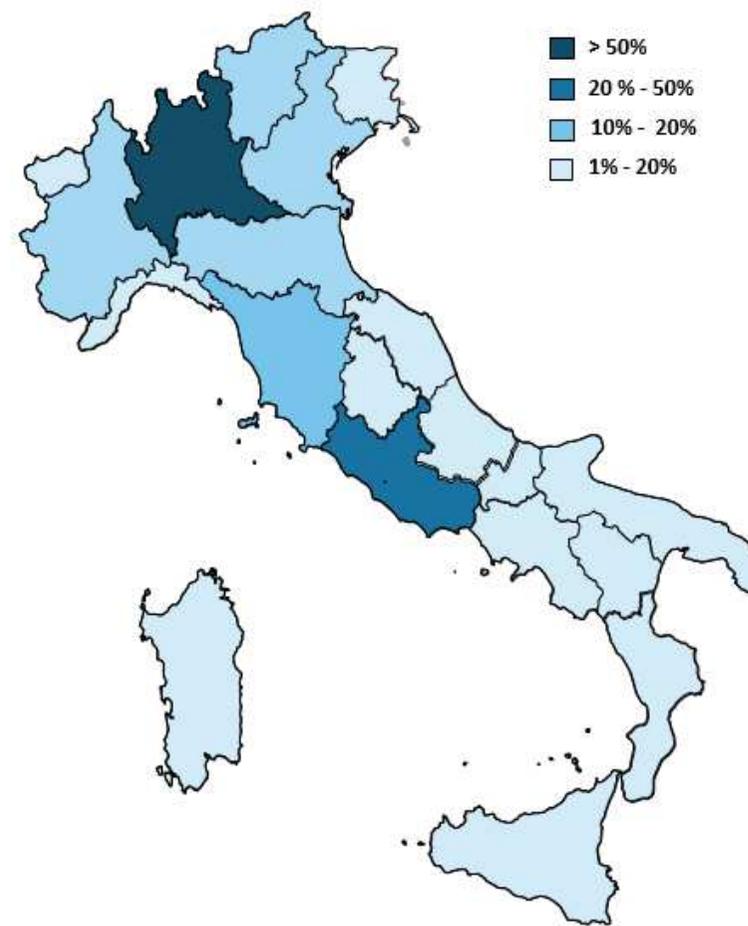
THE BIOTECH SECTOR IN LOMBARDY: TURNOVER



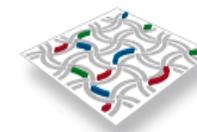
**INVEST IN
LOMBARDY**

Lombardy produces more than **50%** of the Italian **Biotech Industry turnover**

Italian Regions	Biotech turnover
Lombardy	50,2%
Emilia – Romagna	2,2%
Lazio	27,1%
Piedmont	3,1%
Veneto	1,9%
Tuscany	12,4%
Friuli - Venezia Giulia	0,1%
Campania	0,4%
Sicily	0,4%
Apulia	0,0%
Trentino - Alto Adige	1,2%
Sardinia	0,0%
Marche	0,4%
Liguria	0,00%
Other Italian Regions	0,6%
Total	100%



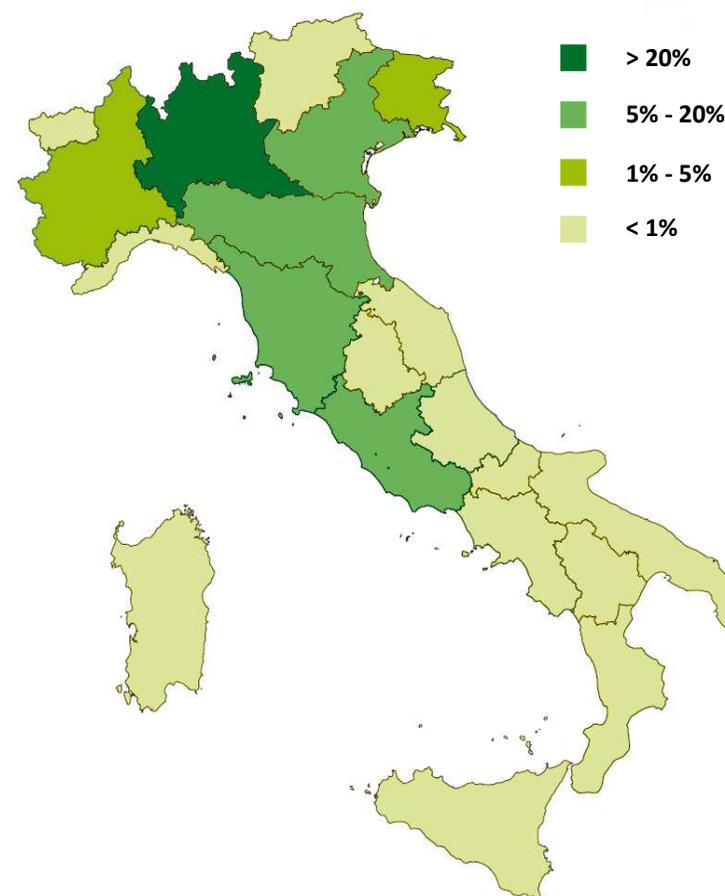
THE BIOTECH SECTOR IN LOMBARDY: INVESTMENTS



**INVEST IN
LOMBARDY**

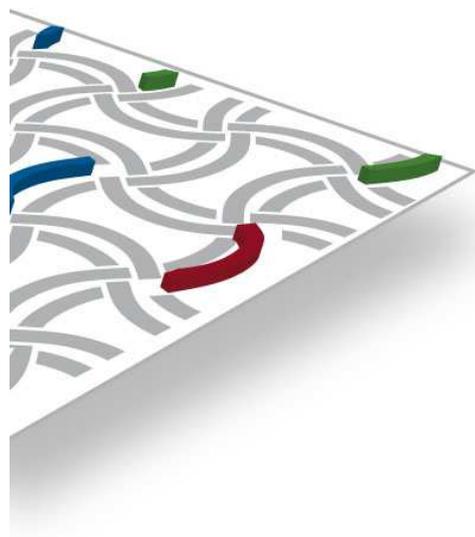
Lombardy is the first region for intra-muros **R&D Investments**, accounting for **51,2%** of the total

Italian Regions	R&D Investments
Lombardy	51,2%
Emilia – Romagna	7,1%
Lazio	17,6%
Piedmont	4,3%
Veneto	6,6%
Tuscany	8,5%
Friuli - Venezia Giulia	1,0%
Campania	0,8%
Sicily	0,7%
Apulia	0,3%
Trentino - Alto Adige	0,5%
Sardinia	0,9%
Marche	0,1%
Liguria	0,1%
Other Italian Regions	0,4%
Total	100%



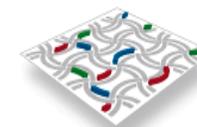


**INVEST IN
LOMBARDY**



LOMBARDY: LIFE SCIENCES FACTS AND FIGURES

LIFE SCIENCES IN LOMBARDY 1/3



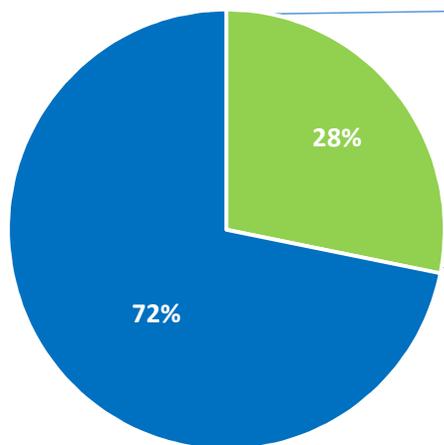
INVEST IN LOMBARDY

Italy is one of the **global leaders in the Life Sciences industry**: the value of production in 2014 amounted to **€198 billion** and employed **1,7 million people**, for a net investment flow of **€7,5 billion**. Within this framework of excellence, and with reference to the European context, **Lombardy is a leading player**

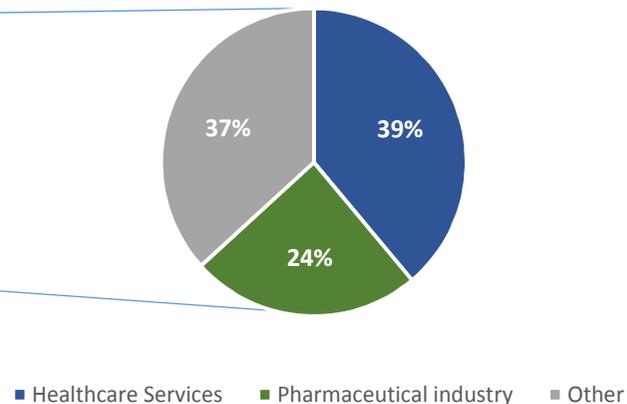
Lombardy generates a **€ 55,8 billion value of production**, equal to **28%** of the Life Sciences Italian industry, with more than **240,000 employees**

Within Lombardy, the **Healthcare Services** sector's **value of production** accounts for **€ 21,7 billion** of turnover, whilst the **Pharma Industry** for **€ 13.6 billion**

Value of Production

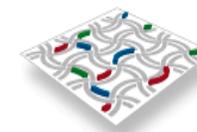


Value of Production



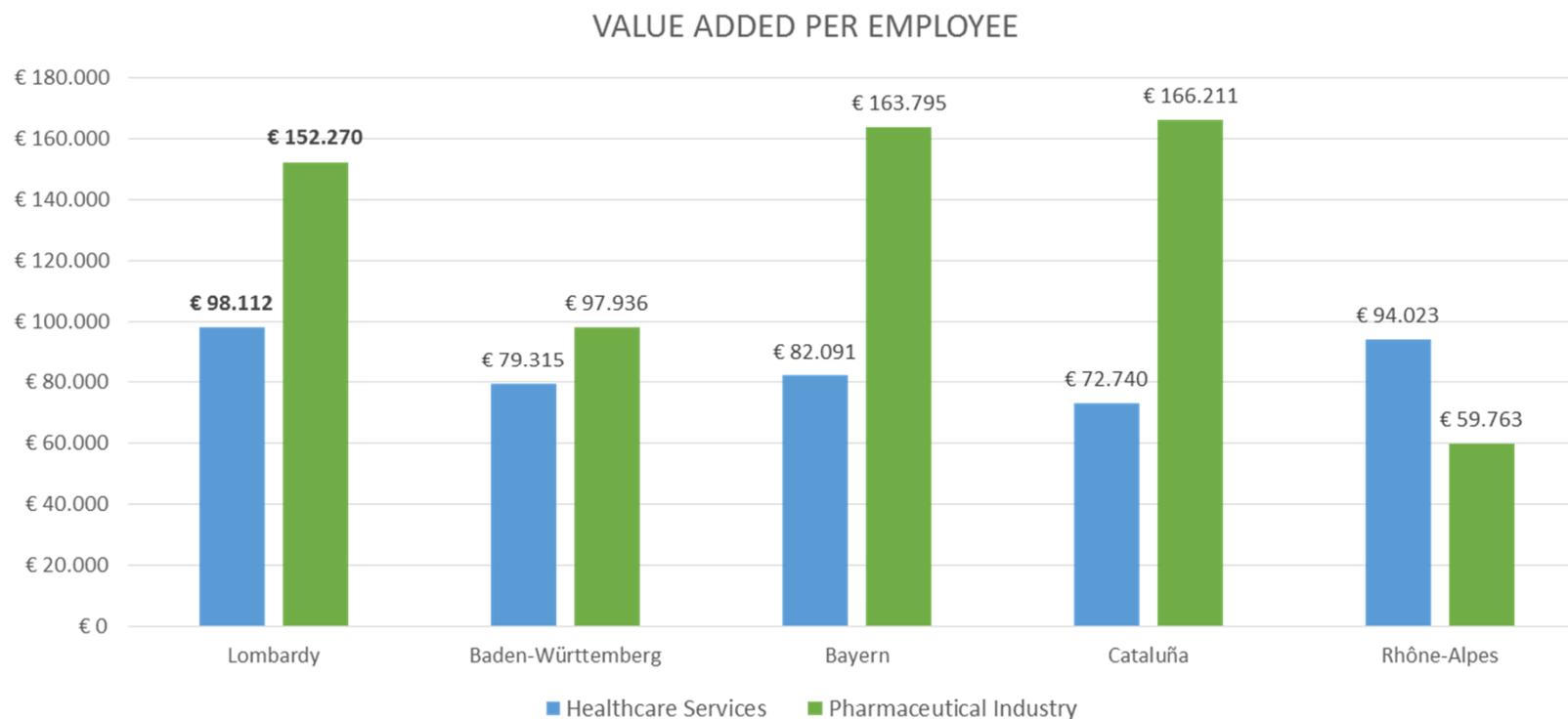
■ Lombardy ■ Other Italian Regions

LIFE SCIENCES IN LOMBARDY 2/3

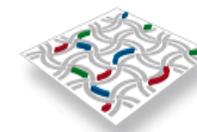


**INVEST IN
LOMBARDY**

Thanks to an excellent and talented workforce, the **value added per employee** nearly reaches **€100.000** in the Healthcare Services, **the highest value among the top 5 European regions for life sciences**. The Pharma industry generates **€152.270** of value added per employee. Both these values are considerably higher than the labour cost per employee



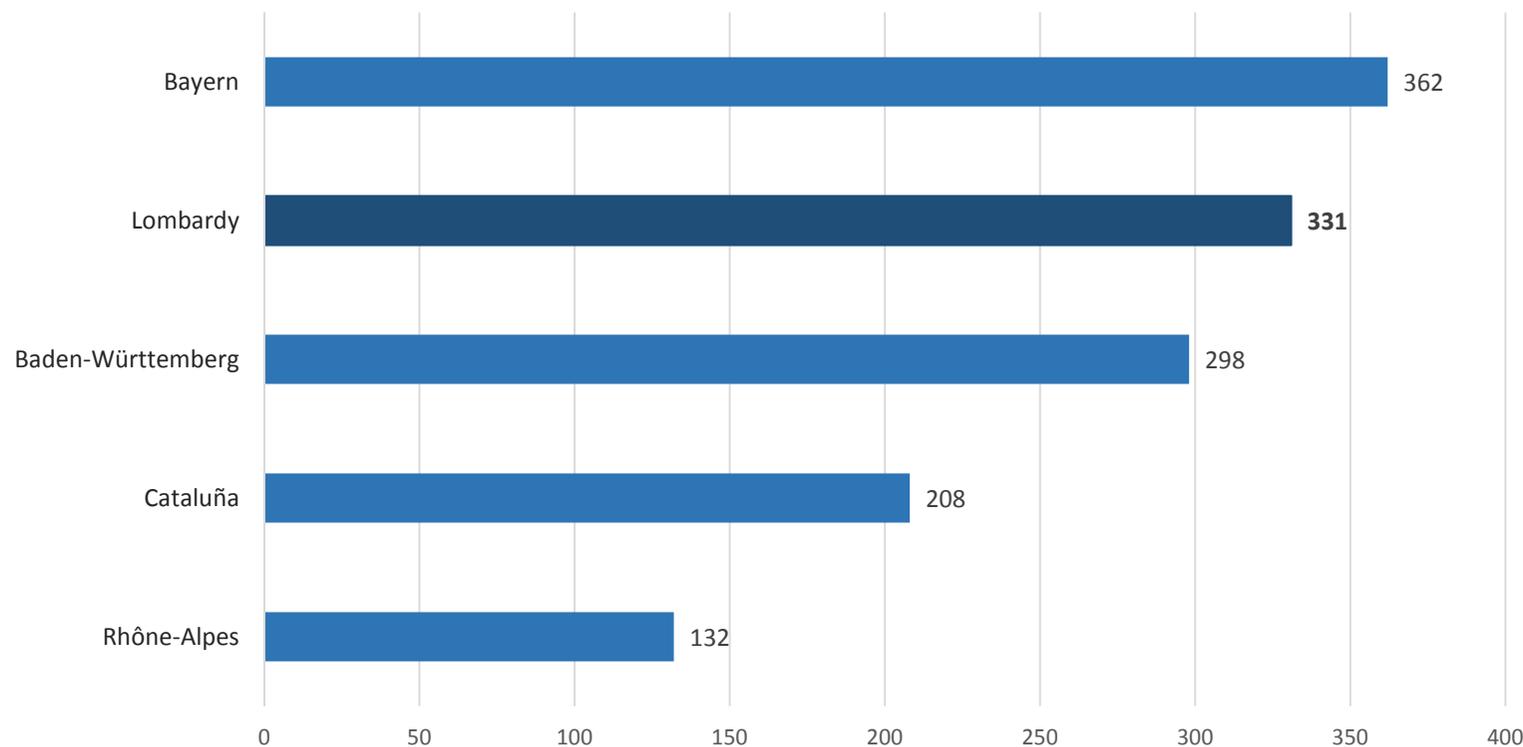
LIFE SCIENCES IN LOMBARDY 3/3



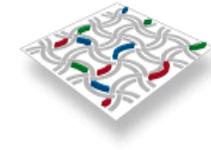
**INVEST IN
LOMBARDY**

Lombardy offers a **thriving ecosystem** in terms of quality of **research and academic production**. Amongst the **top 5 European regions for Life Sciences**, the universities of **Lombardy** rank **2nd** in terms of summation of the **“Life Sciences and Medicine”** scores in the QS 2017 World University Ranking

QS scores in the 2017 World university Ranking



FUTURE PERSPECTIVES: THE HUMAN TECHNOPOLE



INVEST IN
LOMBARDY

- An incubator, a hub, a cluster, “a **national cross-disciplinary research project**” in Milan’s EXPO site to **enhance the Italian excellences** and make Italy the world leader in the **New Biotech Revolution**
- Focus on ‘**4P medicine**’: **P**ersonalized, **P**redictive, **P**reventive, **P**articipative

Human Technopole

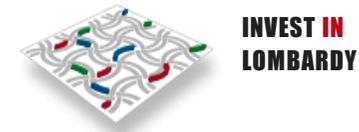


7 research centres, 3 facilities, 1.500 people over 30.000sqm by 2024

THE CENTRES

- Onco Genomics
- Neuro Genomics
- Agrifood & Nutrition Genomics
- Data Science
- Computational Life Sciences
- Analysis, Decisions and Society
- Smart Materials & Devices

FUTURE PERSPECTIVES: THE CITY OF HEALTH AND RESEARCH



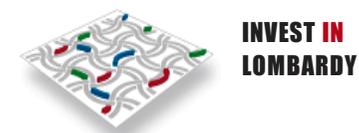
MILANOSESTO

- Masterplan designed by Renzo Piano
- Mixed-use development of ca **1,400,000 sqm of private surfaces** for more than 1,400,000 sqm of land area
- **A new Hospital and Centre of Medical Research with European visibility** (“Città della Salute e della Ricerca”) totally funded by Public Administration
- **A New Graduate School in Oncology and Neuroscience**

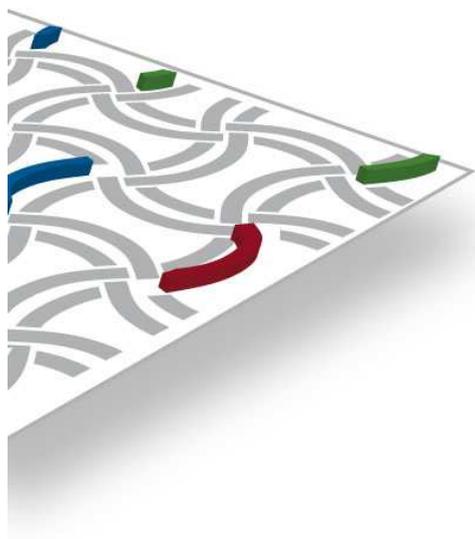


THE CITY OF HEALTH AND RESEARCH

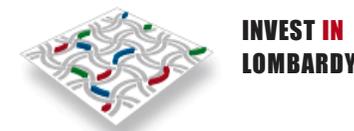
- The new hospital centre will house two centres of excellence the *Carlo Besta Neurological Institute* and the *Istituto Italiano dei Tumori* on a new building of **almost 129.000 square**
- The **largest cancer and neurology research centre in Italy**
- **700 beds**
- **3.000** healthcare workers
- **Cutting-edge** technology
- **Dedicated facilities** for companies (Life Science and pharmaceutical)



ITALY AND LOMBARDY TODAY: INCENTIVES AND REASONS TO INVEST



THE 2017 BUDGET LAW: OPPORTUNITIES FOR COMPANIES (1/2)



- **SUPER-DEPRECIATION**

A **temporary accelerated depreciation regime** has been Introduced, providing a **40% extradeduction** - for depreciation purposes – of the acquisition costs of new tangible assets purchased. Therefore, the company would realize a **net saving of 9,6%** on the investment made. The provision applies to new assets purchased by 31/12/2017 or 30/6/2018, provided that the orders have been signed by 31/12/2017



- **HYPER-DEPRECIATION**

An even more generous **accelerated depreciation regime for new high-tech** tangible and intangible **assets**, functional to the digital transformation of Italian enterprises.

For these assets, the acquisition cost is **increased by 150%** for depreciation purposes. In case of purchases exceeding Euro 500.000, in order to benefit from this favourable regime, companies are required to obtain a certification from an expert to declare that the assets fall within the ones listed in Law 232/2016

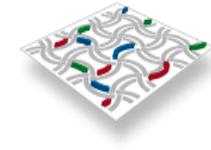


- **« NUOVA SABATINI »**

This measure, provided to all companies interested in upgrading industrial plants, buying new machinery and equipment, investing in hardware, software and digital technologies, consists in a **Financial Contribution** (at a **2.75% rate for 5 years**) to cover the interest payable on bank loans, ranging between Euro 20,000 and Euro 2,000,000.



THE 2017 BUDGET LAW: OPPORTUNITIES FOR COMPANIES (2/2)



INVEST IN
LOMBARDY

• TAX CREDIT ON R&D

A **tax credit** to all enterprises is available **for R&D expenses**.

The main activities eligible for the R&D tax credit are:

- *basic research*
- *applied research*
- *experimental development*
- *manufacturing and testing of products, processes and service*

The tax credit is **equal to 50%** of the qualifying expenses incurred as from 1/1/2017 over the yearly average of such qualifying R&D expenditures that the enterprise has incurred in the 3 fiscal years preceding the fiscal year as at 31 December 2014



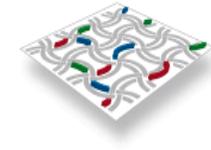
• PATENT BOX

Opportunity to choose a facilitated fiscal regime: **exemption from overall income of 50% of profits** coming from direct / indirect use of specific intellectual property

(DM MEF-MISE 30 July 2015)



THE 2017 BUDGET LAW: OPPORTUNITIES FOR INDIVIDUALS



INVEST IN
LOMBARDY



NEW ITALIAN RESIDENTS

Individuals who transfer their fiscal residence to Italy may be qualified for the new “substitute-tax” regime, on all sources of income located abroad. The **annual substitute tax amounts to Euro 100.000**. Possibility to extend the regime to each family members who transfer their residence to Italy. In this case, annual substitute tax to Euro 25.000.



GOLDEN VISA & FAST-TRACK VISA FOR INVESTORS

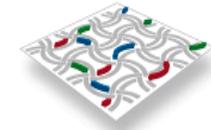
Under specific conditions a non-UE citizen may obtain a **temporary visa** (2 + 3 years) to stay in Italy. Foreigners who wish to invest in Italian companies, innovative startups or Italian government bonds, or who want to make philanthropic donations for the Italian scientific research, can benefit from a special 2-year regime to extend their stay beyond the standard three months.



SPECIAL FISCAL REGIME FOR ‘HIGHLY-SKILLED PEOPLE’ MOVING TO ITALY

A **three-year tax exemption on 90% of the remuneration** for qualified employees (professors and researchers), and a five-year 50% tax exemption for managers and professionals

THE OPPORTUNITIES FOR INNOVATIVE STARTUPS



**INVEST IN
LOMBARDY**



Free-of-charge incorporation with digital signature



Easier to cover systematic losses



Easier access to bank loan



Easier compensation of VAT credit



No regulations on dummy companies



Incentives to investment



Fail-fast

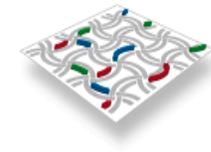


Equity crowdfunding



ITA Support for Internationalization

THE OPPORTUNITIES FOR INNOVATIVE SMEs



**INVEST IN
LOMBARDY**



Free access to #ItalyFrontiers



Flexible corporate management



Easier to cover systematic losses



Exemptions on dummy companies



Incentives to work for equity schemes



Incentives to investment



Equity crowdfunding



Easier access to bank loans



ITA Service Card

A MODERN, COMPETITIVE AND NON-DISCRIMINATORY LABOUR MARKET



In the **last decade**, Italy has implemented a number of **substantial reforms of labour market** aimed at the creation of a **modern, competitive and non-discretionary environment**



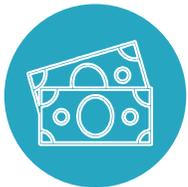
Limited Reinstatement

Since 2015 reinstatement has been limited to cases of discrimination proven by the concerned employees. The due indemnity is not discretionary for the judge



Court litigation

the court litigation has dramatically fallen (approx. 70% reduction of court cases concerning dismissals and end of fixed term)



Indemnity

With the new reform, should the dismissal be declared unfair, the employee is entitled to an indemnity amounting to 2 months' salary per each year of seniority



Length of Court litigation

the length of first degree employment Court litigation: 1-1.2 years on average at Italian level; 7 months at the Court of Milan;



Out of court settlement

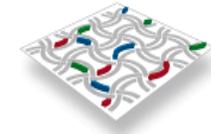
The new law on dismissal encourages the parties to find a prompt and amicable out of court settlement. Example: should the employee accept an offer of 1 month per year of seniority, up to a maximum of 12 months, a substantial tax exemption applies



New powers for the employer

since 2015, the employer has a wide power to freely decide the duties to which the employee must be assigned to during the employment relationship

INVEST IN LOMBARDY PARTNERS



INVEST IN LOMBARDY



STUDIO PALMA DEBERNARDI BORGHI
E ASSOCIATI
COMMERCIALISTI
MOORE STEPHENS



Pirola
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Zei
& Associati
studio di consulenza
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**INVEST IN
LOMBARDY**

Find out more

Invest in Lombardy is the regional service for attracting foreign investments into the Lombardy region.

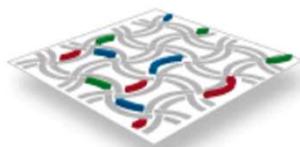
Invest in Lombardy is structured as a regional network that works closely with business communities and helps address their needs.

Want to invest in Lombardy?

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