

REPORT  
**biocat**

The life sciences and  
healthcare sector in  
Catalonia

# 2021 BioRegion Report

2021

#BioRegionReport

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# 2021, an exceptional year. Growth drivers and opportunities landscape for the BioRegion

2021 was possibly the year with the greatest efforts channeled into healthcare innovation globally and, particularly, into the Catalan life sciences and healthcare ecosystem. The 2021 BioRegion Report covers this exceptional time from different perspectives, highlighting the record impact on Catalonia's wealth in percentage of the GDP, positive evolution of other macroeconomic indicators (such as employment and turnover) and, also, a variety of increasing international investment rates and rounds. This fast growth, also seen worldwide, has an additional byproduct: The myriad of opportunities in healthcare innovation we'll see in the coming years. COVID-19 has invigorated the industry, accelerating the use of therapeutic strategies and digital technologies that are bringing about the long-heralded transformation of the healthcare industry. And investors have turned to startups as a disruption-proof asset.

It is in the international arena that the Catalan life sciences and healthcare ecosystem is scaling up, and on the challenges and opportunities that 2021 helped define, where we put the forward-looking focus of this BioRegion Report. In the 2020 edition, we looked at the ecosystem's challenges ahead: technology transfer, talent development and acceleration, capital mobilization and investment attraction,

technology adoption by the public healthcare system and business consolidation. These challenges are all still fully valid, but in this edition we wanted to look forward, scanning the horizon not only of the ecosystem but also of Europe and the world.

On one hand, the EU's strategic decisions in 2021 targeted shaping and providing content for the two flagship concepts of the period: recovery and resilience, with the twin transformation (sustainable and digital) as the designated pathway. The Green Deal, technological sovereignty, the Circular Economy Action Plan, the European Data Space, innovation with social impact... will profoundly influence the EU's national, regional and local budgetary allocations, and therefore those of all the stakeholders involved.

On the other, there's growing concern worldwide for the impact of climate change on global health, the financial sustainability of healthcare systems (the OECD estimates countries' global average spending was around 10% of GDP in 2020) and the health sector's carbon footprint (almost 5% of global greenhouse gas emissions [World Bank 2017]). The BioRegion will scale up in this arena of EU Next Generation funds, the UN's COP26 commitments, telemedicine, personalized medicine, access to health data, patient-centered care and

the challenges of public and global health, just to mention some of the issues and uncertainties on the horizon ahead.

Looking forward inevitably leads us to see how we can facilitate access to digital technology and the adoption of innovation in general by healthcare systems. The leading countries in this area are already implementing their own legislation to make regulatory aspects more flexible and to speed up and simplify the path of bringing health innovations into the healthcare area.

## What assets does Catalonia have to help it stay ahead of the curve in a more digitalized, innovative, sustainable, circular and socially inclusive environment?

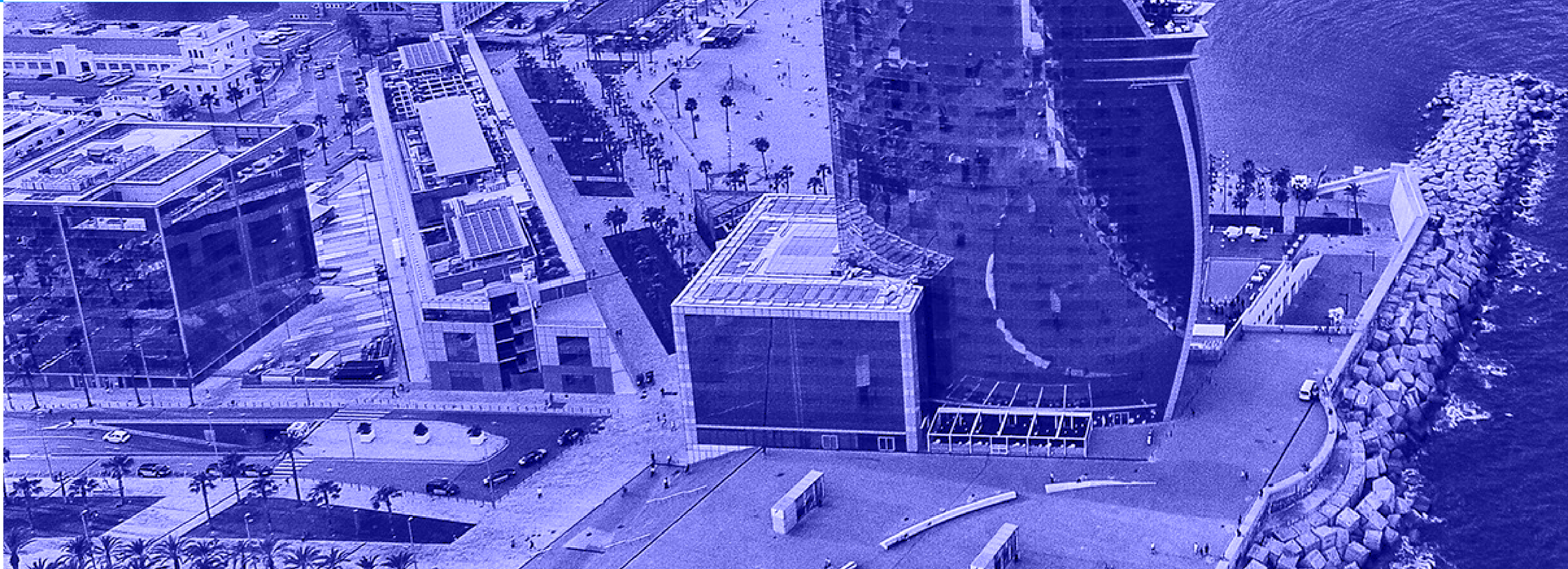
Catalonia has one of the leading life sciences and healthcare ecosystems in Europe, with 91 research centers and over 1,300 companies that, despite the pandemic, haven't ceased to provide good news for the sector. A sector that already makes up 8.7% of the Catalan GDP, employs about 9% of the working population and generates €37.7 billion, counting

companies from the sector and healthcare services. An industry that exports over 50% of the products from Spain, and a startup fabric that is getting larger every day, with noteworthy growth in the medtech and digital health subsectors, which have played a key role during the pandemic. With entrepreneurial teams, highly qualified researchers and a solid group of specialized investment funds that attract more and more international VCs and have contributed to raise a grand total of €238 million in investment in innovative startups, again setting a new annual record for investment in the sector. An ecosystem with a solidity in terms of public-private partnerships that is most often found in the mature systems of Europe's leading countries. With a healthcare system in transformation, embracing enabling technologies, for which Catalonia has a number of cutting-edge centers. And with all the ingredients in place to become a leading European hub in emerging therapies and personalized medicine that stands to benefit from a large share of the EU Next Generation funds that Catalonia receives.

Given all the above, the sector needs the still prevailing challenges to be addressed with this forward-looking gaze that is essential to boosting its competitiveness and taking it to the place it deserves, in Europe and the world.



**01**  
**General  
overview and  
key indicators**



# The BioRegion of Catalonia: a driving force in healthcare innovation

The BioRegion, the life sciences and healthcare ecosystem in Catalonia, is considered one of the top innovation hubs in Europe and is based on excellent research, a quality higher-education system and a network of talent, institutions, investors and companies that perform cutting-edge research and provide the sector with innovation and services.

The sector has 91 research institutions and over 1,300 companies (mainly biotech and pharma, but also medtech and digital health firms) that, together with healthcare services, generate 8.7% of the Catalan GDP\* (4.4% industrial subsector and 4.3% healthcare services) and employ 244,000 people, over 8% of the total working population of Catalonia. 91% of the companies in the BioRegion are located in Barcelona.

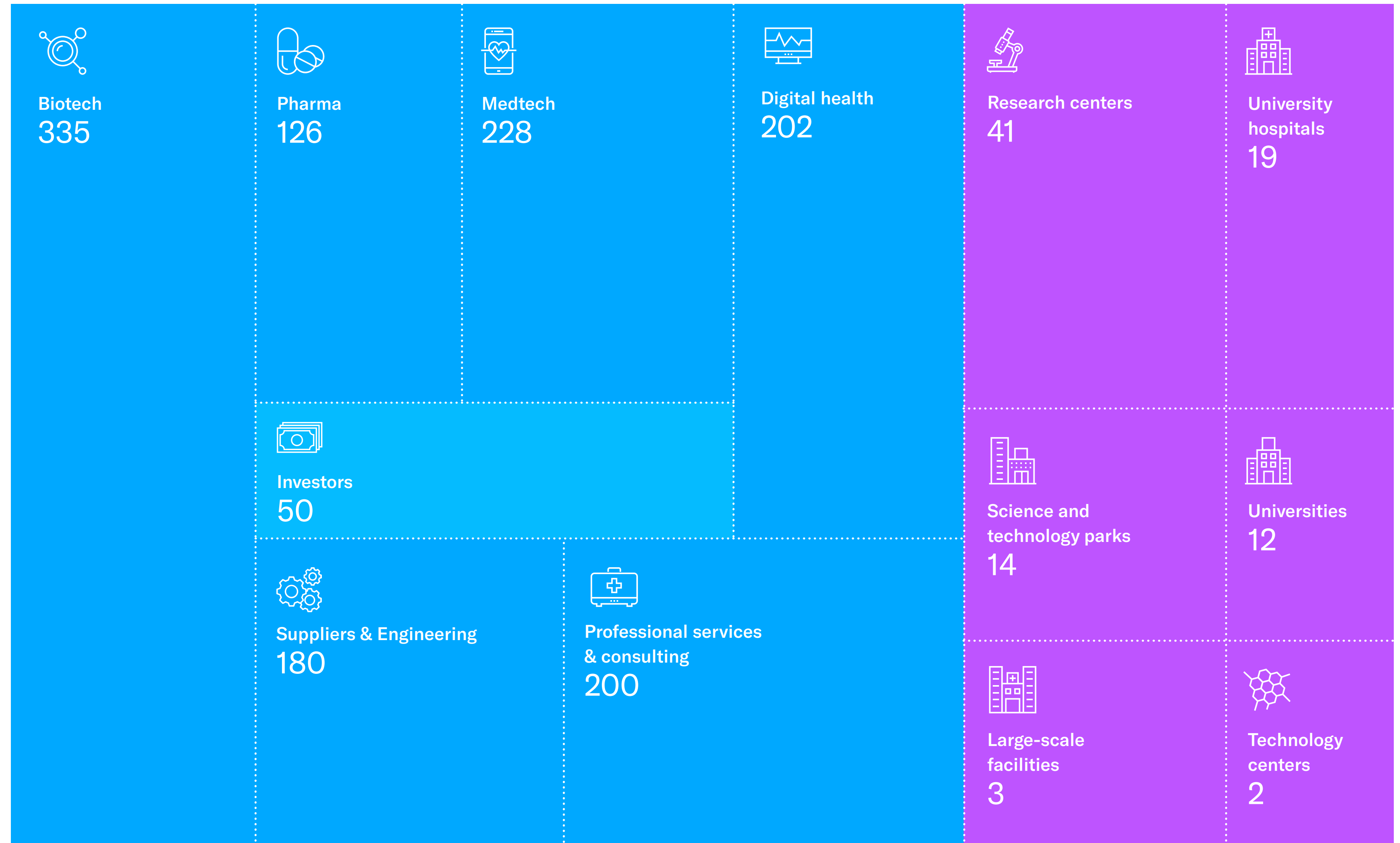
In 2021, despite the pandemic, the ecosystem's innovation indicators showed sustained growth (company creation ratio, investment attracted, employment, patents, pipeline, etc.), as this Report reflects.

\* Compiled internally from Biocat and SABI 2020 data for each industrial subsector and Idescat 2018 for healthcare activities

## Map of the ecosystem of the BioRegion of Catalonia

+1,300 companies ↘

91 research institutions ↘



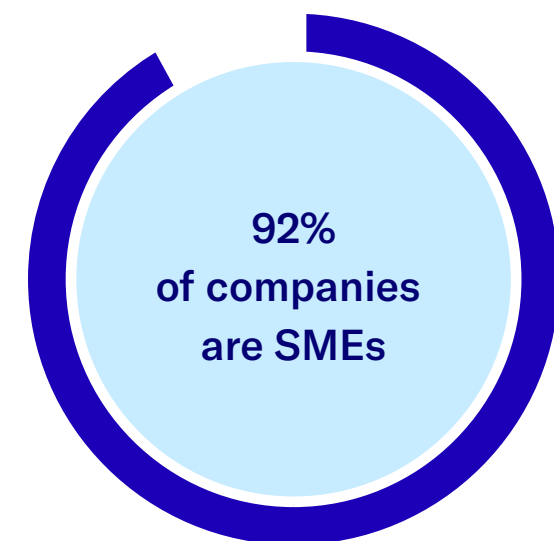
Source: Biocat



# Sustained growth of macroeconomic indicators

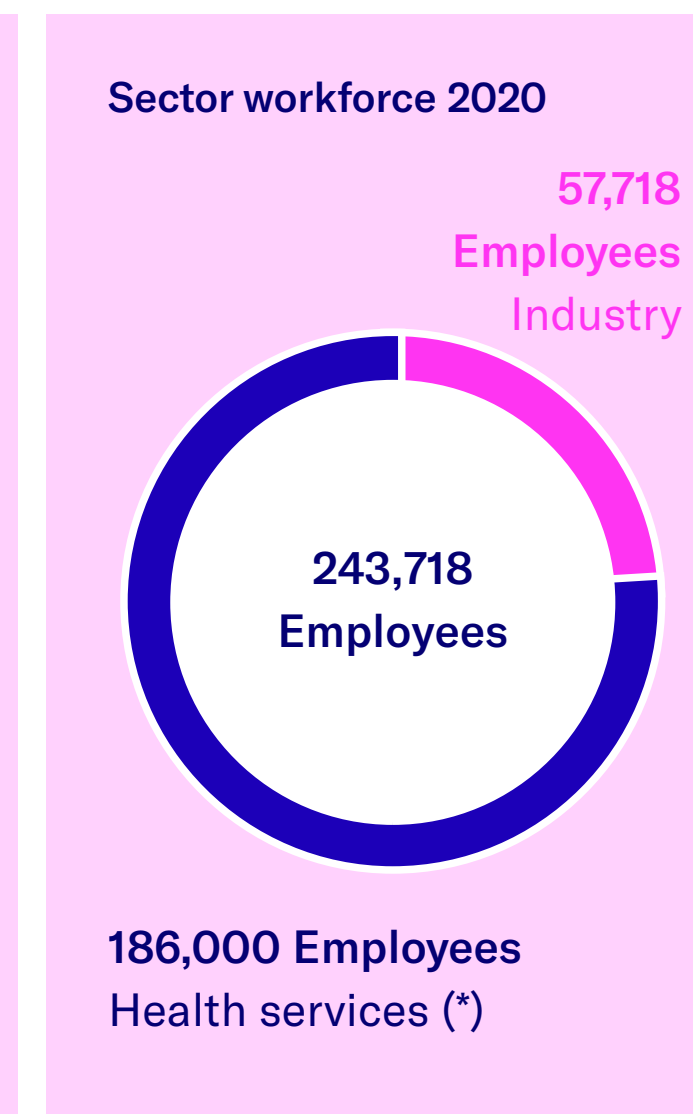
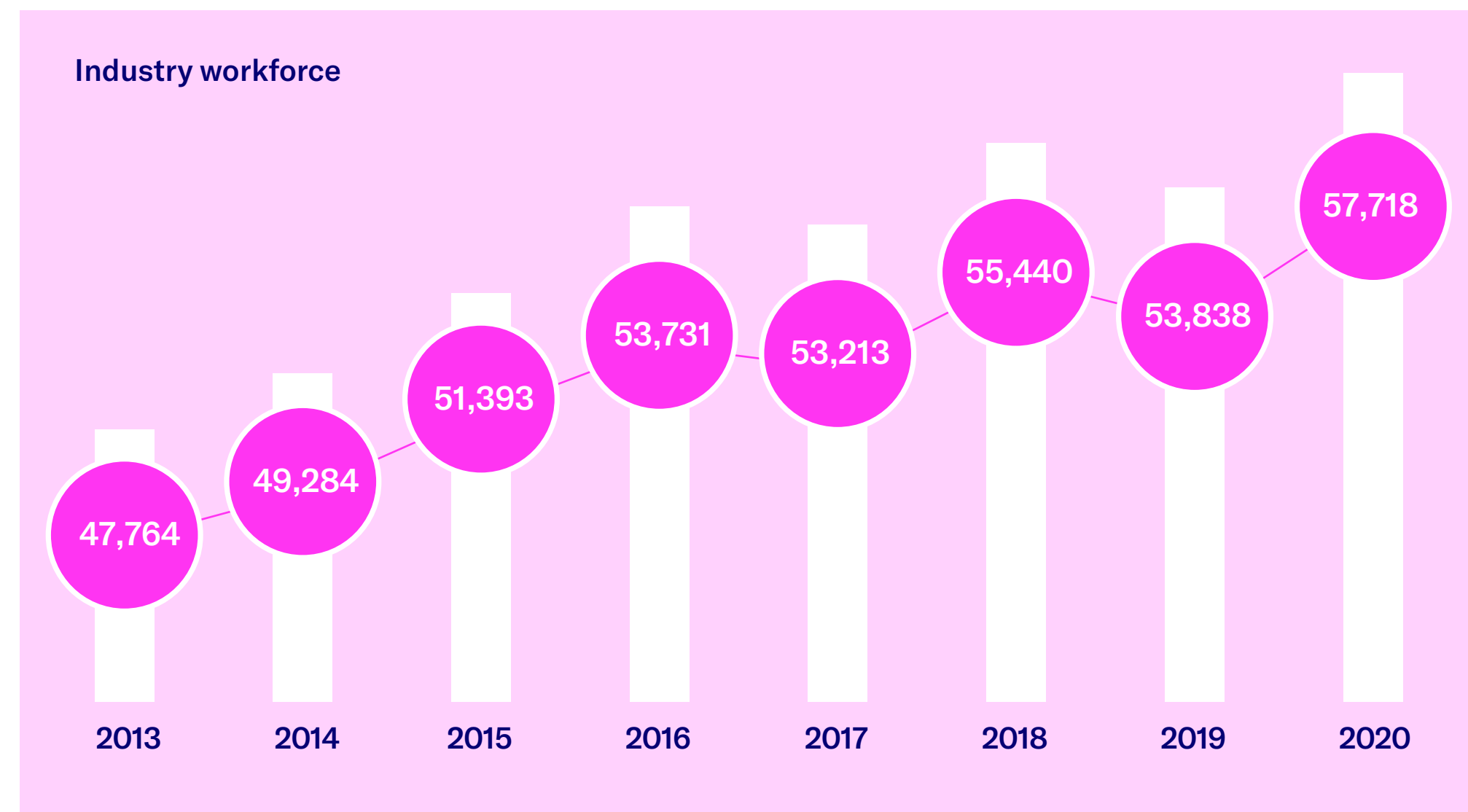
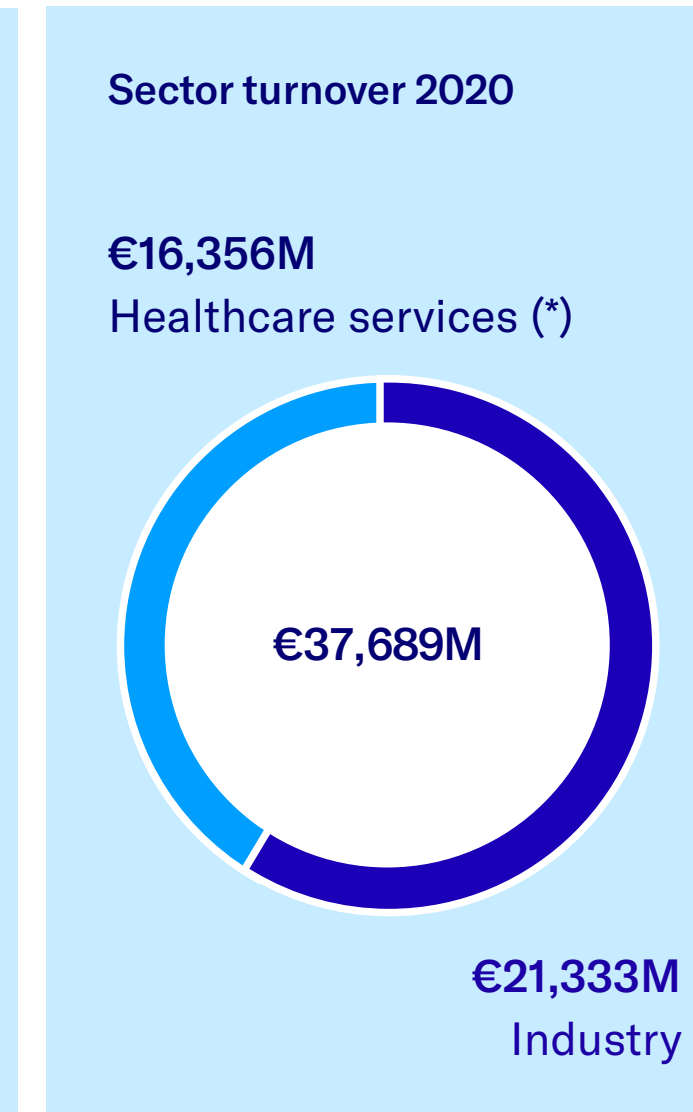
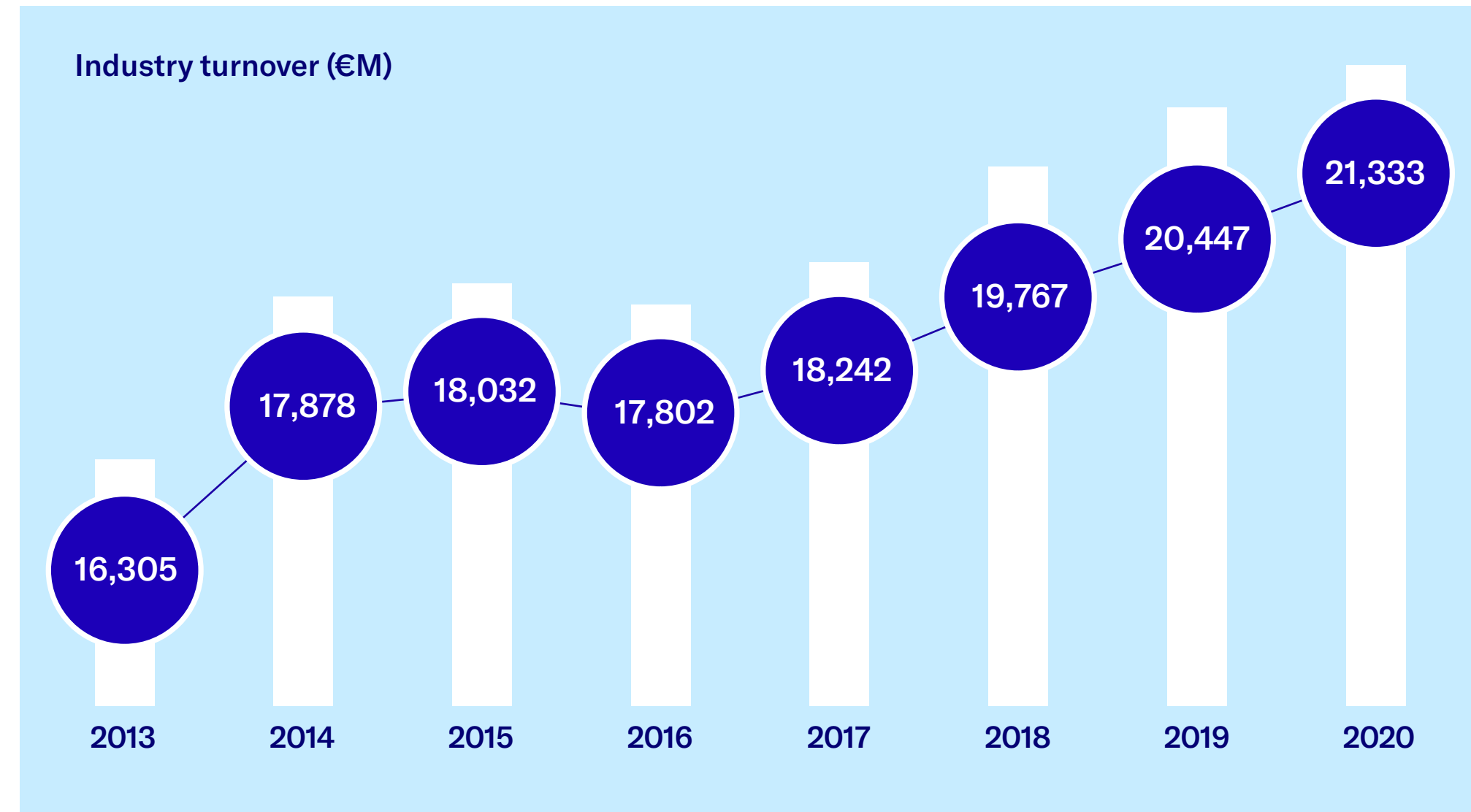
In 2020, turnover continued to grow at the same annual rate (CAGR) as the past 10 years (roughly 3%), while employment rose 9%, well above the yearly average of 2%.

As a subsector, pharma has the fewest companies but their joint turnover is 2.5 times higher than biotech firms. In terms of the business volume of these biotech companies, it is worth noting those working in human health/therapies (2% of joint turnover), scientific services (37%), and the rest of the companies that use biotechnology in their processes, whether in animal health, agrifood, industry or the environment (61%). The medtech and digital health subsectors stand out for their increased turnover in 2020 (up 40% and 21%, respectively).



Size of companies  
 The bulk of the sector's business fabric is made up of SMEs, which account for 92% of the total. Of these, 78% are micro and small companies and the remaining 14%, medium sized. Evolution of the size of companies has been stable in recent years.

## Macroeconomic indicators



## Industry turnover 2020

Digital health	€311M
Professional services & consultancy	€902M
Suppliers	€2,534M
Medical technologies	€3,574M
Biotechnology	€4,025M
Pharmaceutical	€9,987M

Sources: Biocat, SABI 2020, Idescat 2018

\* Health services: Including the provision of healthcare and social services to health institutions that provide accommodations and offer diagnostic and medical treatments to patients.



# Destinations and weight of exports in the industry

**€7,273M**

Life sciences and healthcare products exported (2020)

**50.6% of Spanish total**

Catalonia exports more life sciences and healthcare products than any other region of Spain

**11%**

Of all Catalan exports

**811**

Companies that regularly export life sciences and healthcare products (2020)

**43.6%**

Of all companies in Spain that export life sciences and healthcare products

## Main destinations of Catalan exports in the sector

1. United States | 2. France | 3. Germany | 4. Switzerland | 5. Italy



## 511 subsidiaries abroad of Catalan companies in the life sciences and healthcare sector


## Top-notch products exported



**Pharmaceutical products**  
92.9%



**Radiation, electromedical and electrotherapeutic equipment** 6.7%



**Medical and dental supplies** 0.2%

## Some of the most important regular exporters\*


\* Regular exporters are companies that have exported for the past four years in a row.



# Foreign Direct Investment in Catalonia (FDI Markets\*)

Catalonia is ranked 9th in Western Europe by CapEx and is the best region to invest in southern Europe, according to the Financial Times.

Investments in the BioRegion by foreign companies in the sector have brought in over €700M in direct investment over the past five years and have created over 3,000 jobs.

The impact on employment is noteworthy, up 56% from the previous five-year period, and is a positive indicator given its connection to attracting and retaining highly qualified talent (main professional profile in this industry).

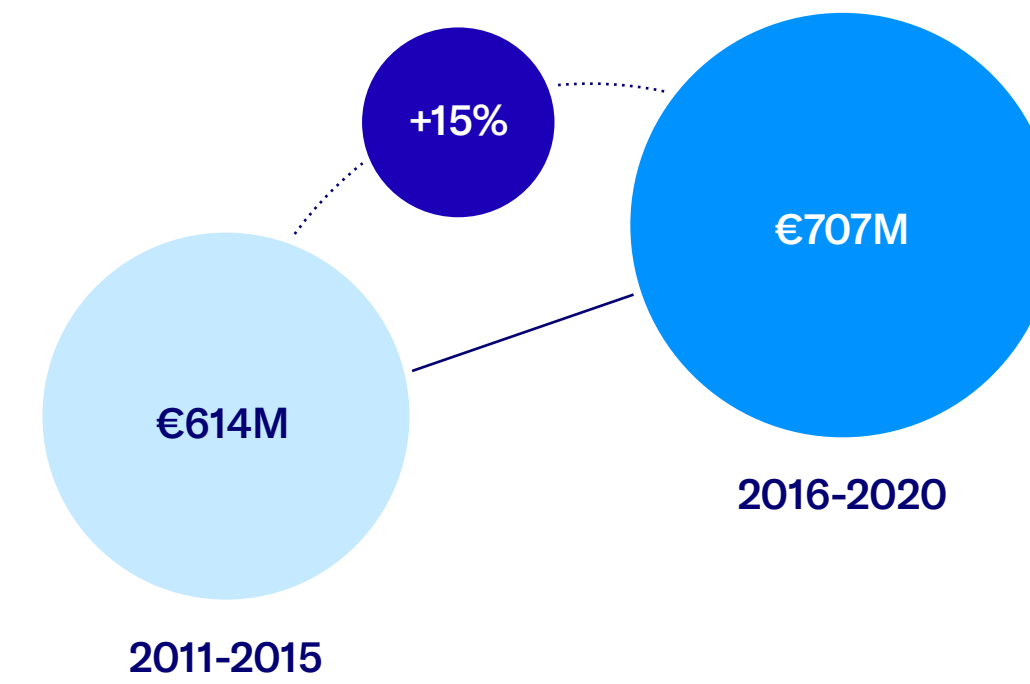
In terms of investment and employment created in Catalonia, the United States, Germany and France stand out.

## Main foreign investment in Catalonia (January 2020 - September 2021)

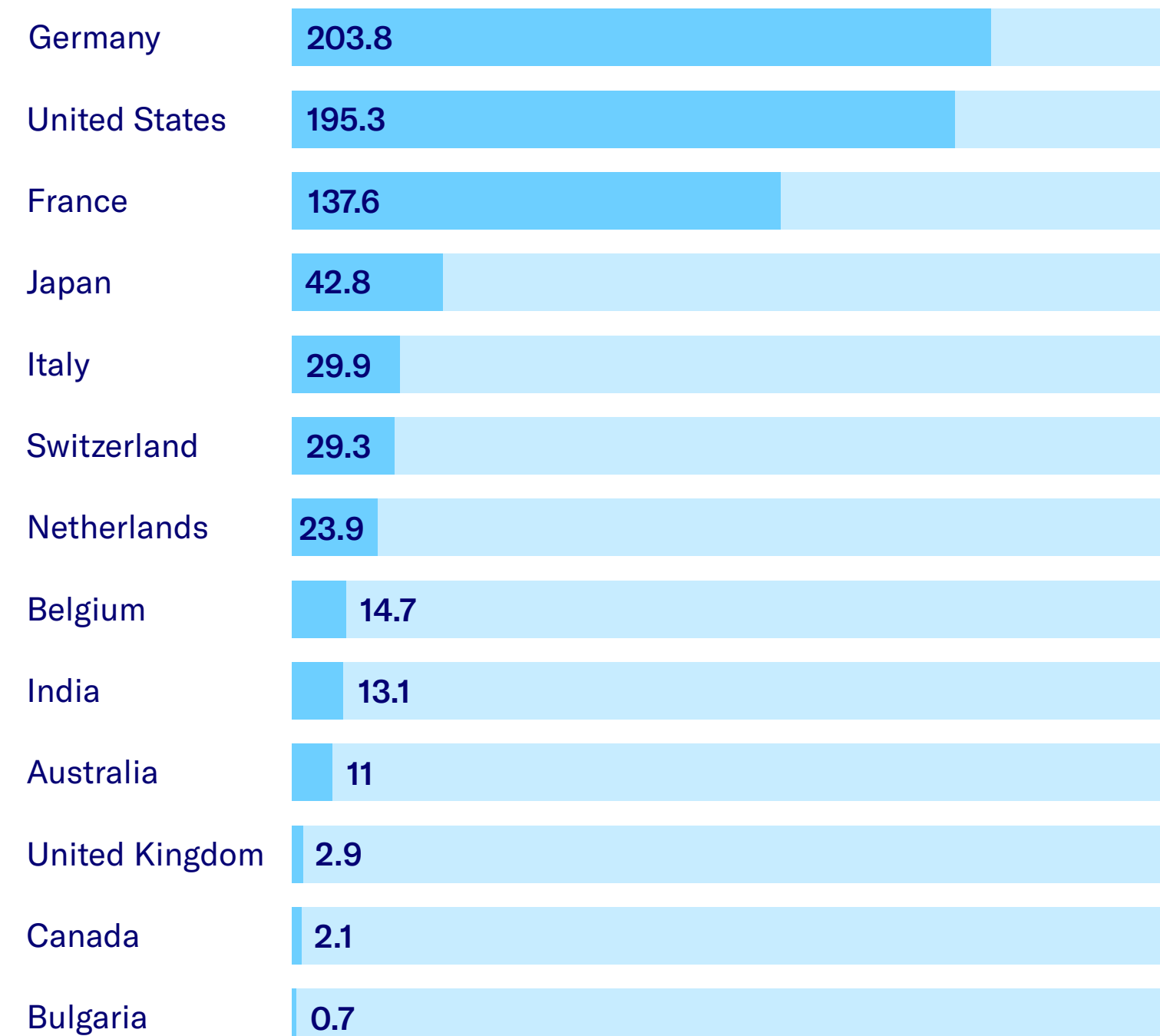
Company	Direct investment (€M)	Jobs
Teladoc Health	120	750
Sandoz	55	123
Qiagen	24	99
AGC Pharma Chemicals	16	42
Scientific Products	14	87

\* FDI stands for Foreign Direct Investment  
 Source: ACCIÓ based on FDI Markets

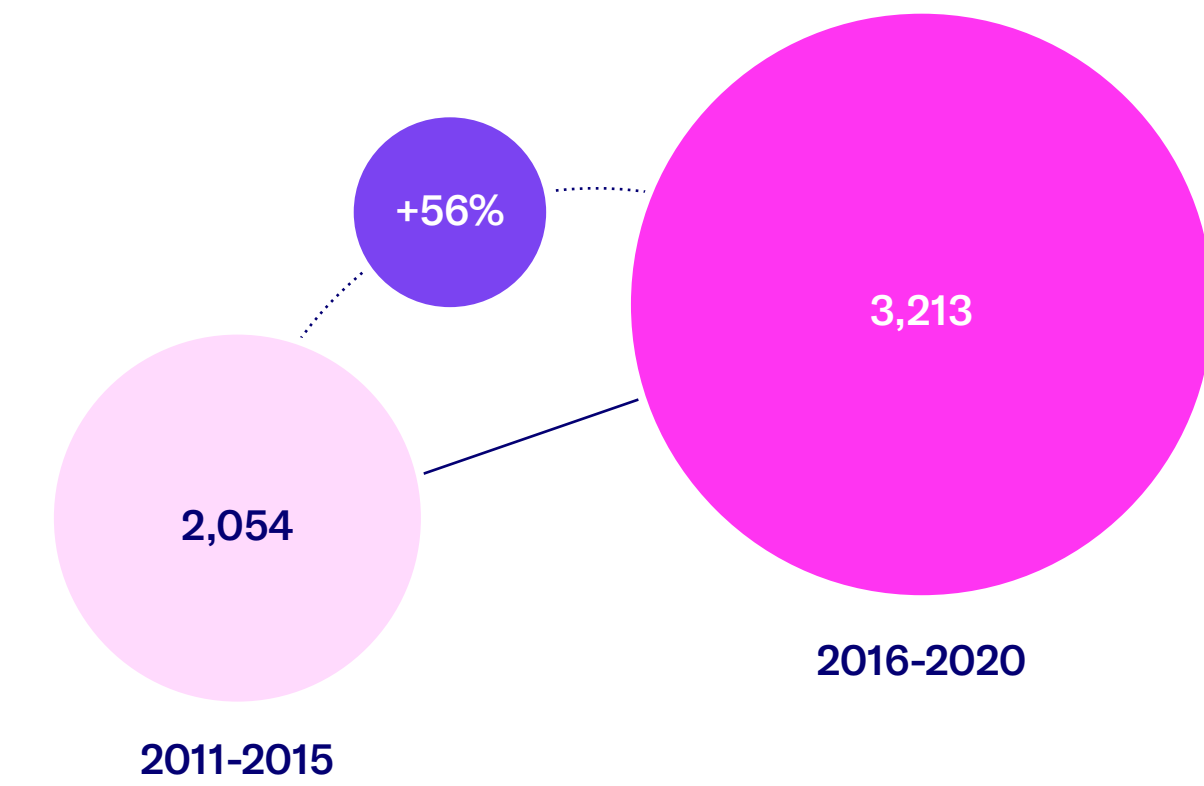
Capital expenditure (CapEx) in the BioRegion by international companies



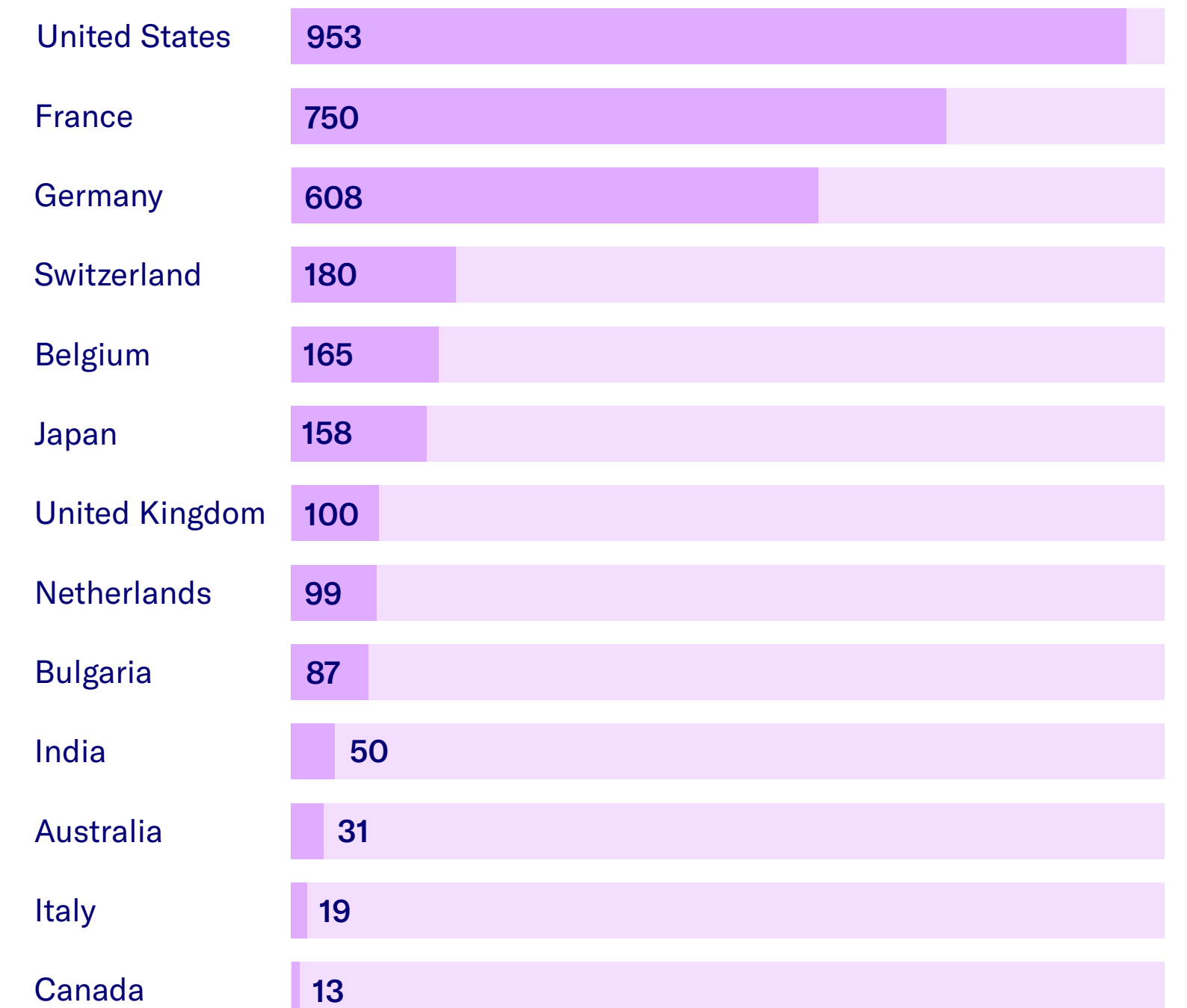
Capital expenditure (CapEx) in the BioRegion by country (€M) (2016-2020)



Jobs created in the BioRegion by international companies



Jobs created by origin of companies (2016-2020)





# Attracting innovation centers and multinational corporations

40% of the top life sciences and healthcare companies have headquarters in Catalonia\*, which is home to 50% of the pharmaceutical industry in Spain.

According to the Financial Times, among a wide range of European cities, Barcelona is considered the most attractive location in southern Europe to invest in an R&D center in the life sciences, and the 3rd most attractive city in Europe for investing in a pharmaceutical manufacturing facility.

What makes Barcelona attractive:

- Competitive property, workforce and public services costs
- Widely available quality facilities
- Highly efficient logistics systems
- Top-notch life sciences and healthcare talent

Barcelona has also become a capital attractive to innovation centers and subsidiaries of large multinational corporations from other sectors, which see the city as one of the most interesting European ecosystems for their hubs of excellence.

## Main foreign companies in Catalonia

Central headquarters in the BioRegion

International companies

Innovation centers established in Barcelona (2018-2021)

\* ACCIÓ, based on Orbis (CNAE 21, 325, 266)

Partial, representative sample of multinational corporations in the BioRegion of Catalonia



# Barcelona, hub of hubs: future talent and excellence nodes in the ecosystem

In 2021, several new initiatives announcing or promoting new facilities and centers in the Barcelona metropolitan area are expected to reinforce the assets of the life sciences and healthcare ecosystem and related technology sectors.

These hubs will help attract talent and new R&D projects (national and international), in line with the dynamic research and innovation activities in the BioRegion.



1. SJD Pediatric Cancer Center Barcelona ↘



Hospital Sant Joan de Déu  
 Barcelona  
 Start date: 2022

2. BSC-REPSOL Building ↘



Government of Catalonia, Ministry of Science and Innovation, UPC, Repsol  
 Inauguration: 2021

3. DFactory Barcelona ↘



Zona Franca of Barcelona Consortium, Leitat  
 Start date: 2021

4. New Hospital Clinic Barcelona ↘



Government of Catalonia, UB, Barcelona City Council, Barcelona Provincial Council  
 Start date: 2022

5. Innovation and Research Hub Mercat del Peix ↘



BIST, CSIC, UPF  
 Project: 2021- 2025

6. Urban Tech Campus Pier HealthTech ↘

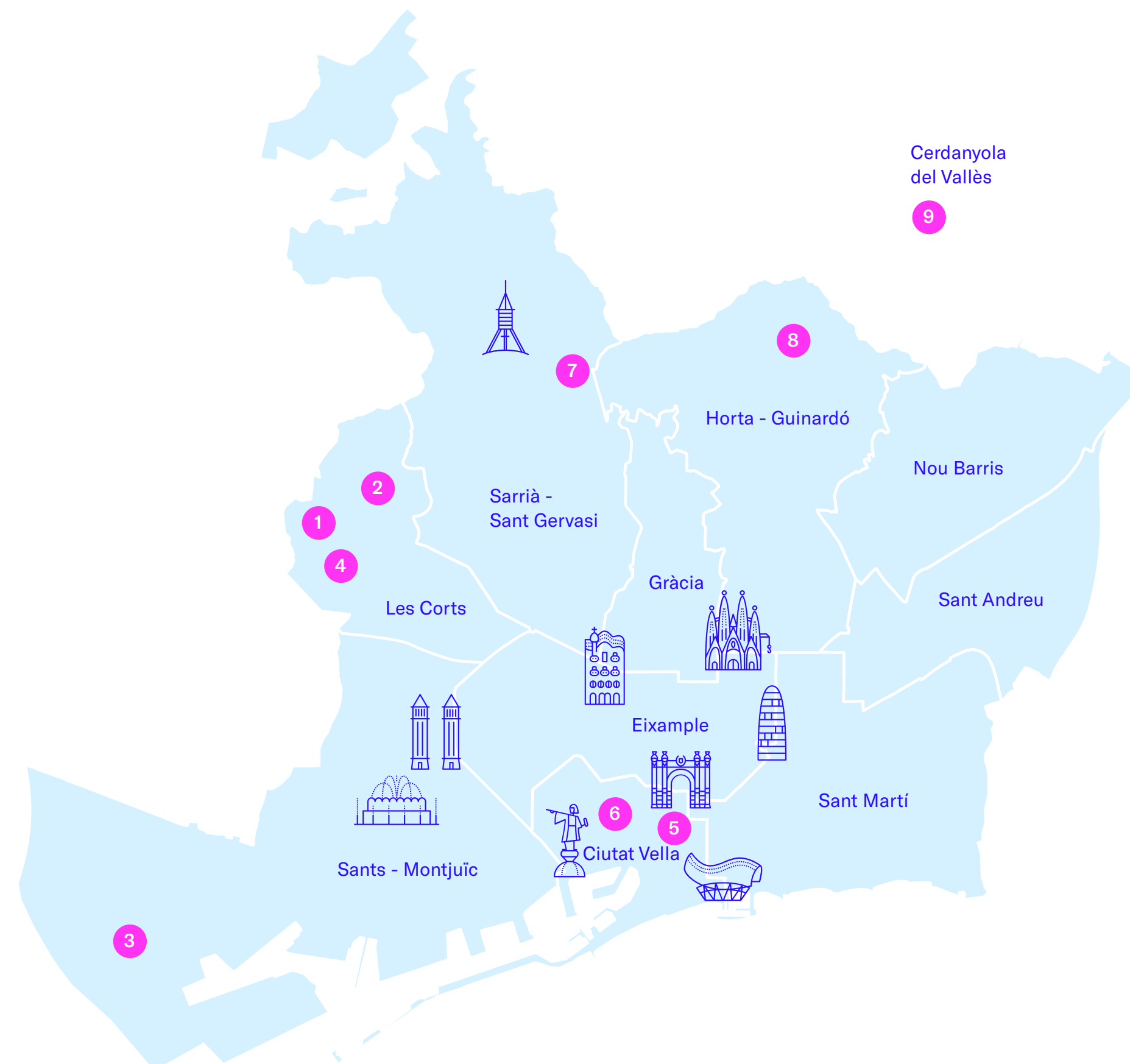


Tech Barcelona  
 Start date: 2022

7. CaixaResearch Institute ↘



La Caixa Foundation  
 Project: 2021-2025



9. ALBA II ↘



Government of Catalonia, Ministry of Science and Innovation, EU  
 Start date: 2021

8. New Vall d'Hebron Campus ↘



Vall d'Hebron Hospital, VHIR, VHIO  
 Project: 2018-2022



# Startups: record in therapeutics biotech firms

Although the overall creation rate has held steady, the predominant type of company has changed over the years. While 2010-2014 saw a surge in biotech companies, in recent years it has been digital health firms that have moved up the ranks. This trend held steady through 2020, when biotech once again became the predominant subsector. A record was also set for the creation of startups working in new therapies.

So, of the 54 startups created in 2020, 23 are biotechnology firms and 15 of them focus specifically on developing therapies, basically in oncology, infectious and respiratory diseases. In the past two years alone, the number of therapeutics biotech companies has grown 31%. The majority are spinoffs from institutions like BSC, ICFO, IDIBAPS, IJC, IGTP, IMIM, IRB, Hospital SJD, UPF, UB and ICREA.

The business creation rate in the BioRegion has held steady at one company per week since 2010.

### 1st Startup Hub in Southern Europe

StartupBlink, 2020

### 2nd hub in the EU by preference of startup founders

Startup Heatmap Europe, 2019

### 6th European city in investment received by startups

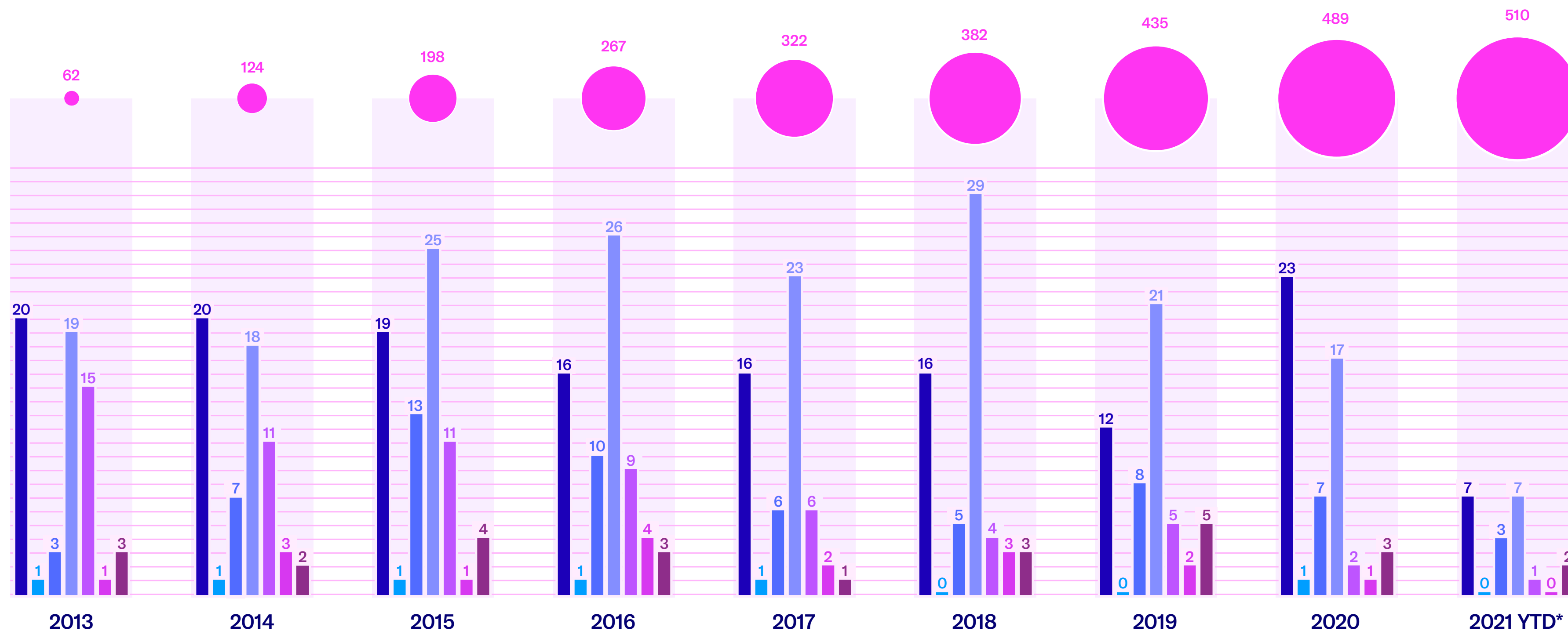
Dealroom, 2021

\* The process of identifying companies' activity doesn't stabilize until the following year, so the 2021 indicators are still incomplete.

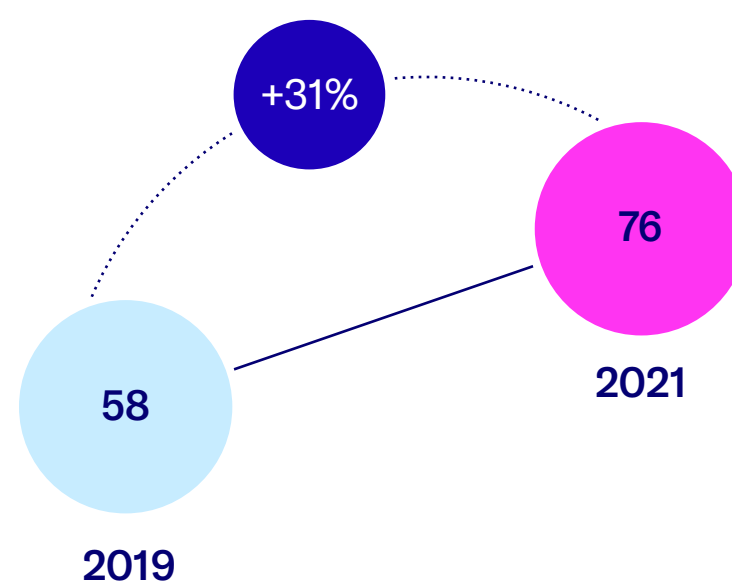
Note: The biotech segment includes therapeutics companies, R&D services and other biotech subsectors like agrifood and industrial.

## Business creation rate in the BioRegion

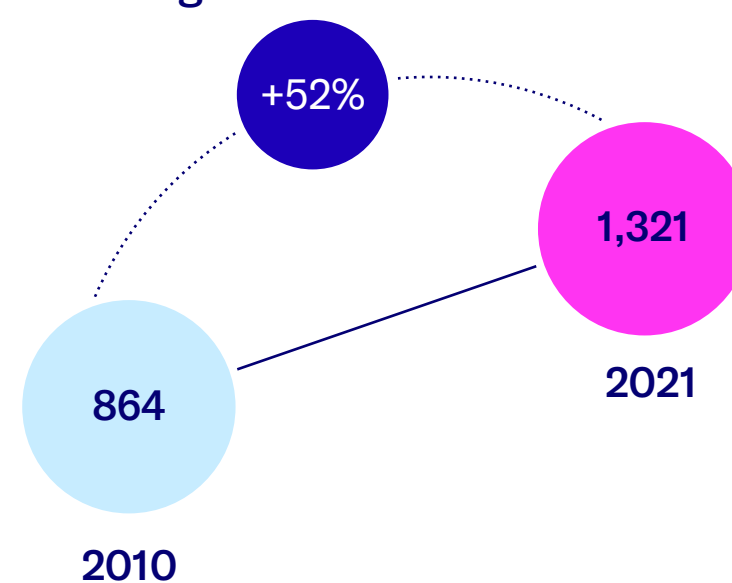
Cumulative companies created | Biotech | Pharma | Medtech | Digital health | Professional services & consultancy | Suppliers & Engineering | Investment bodies



### Growth of therapeutics biotech firms ↘



### All companies in the BioRegion ↘

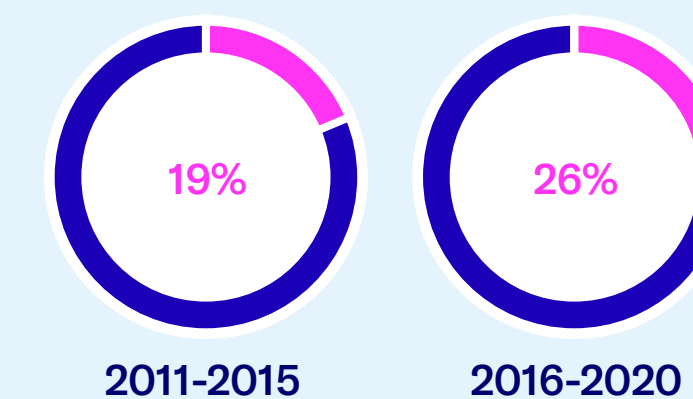


Source: Biocat

### % Startups led by women (C-Suite Level):

Over these two periods, the number of women in executive positions at startups in the sector increased 51% (from 53 to 81 women at the C-Suite level).

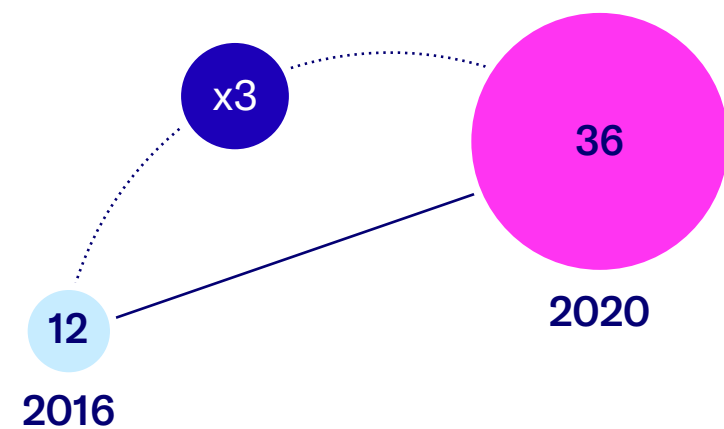
Of the startups created, the segments with the highest percentage of female executives are therapeutics biotech firms with 35% and medtech with 29%.



# Spinoffs: growing in number and investment

After a four-year downward trend, 2020-2021 was one of the most prolific periods in terms of new companies created from universities and health research institutions. They also attracted 48% more investment.

## Spinoffs created in the BioRegion



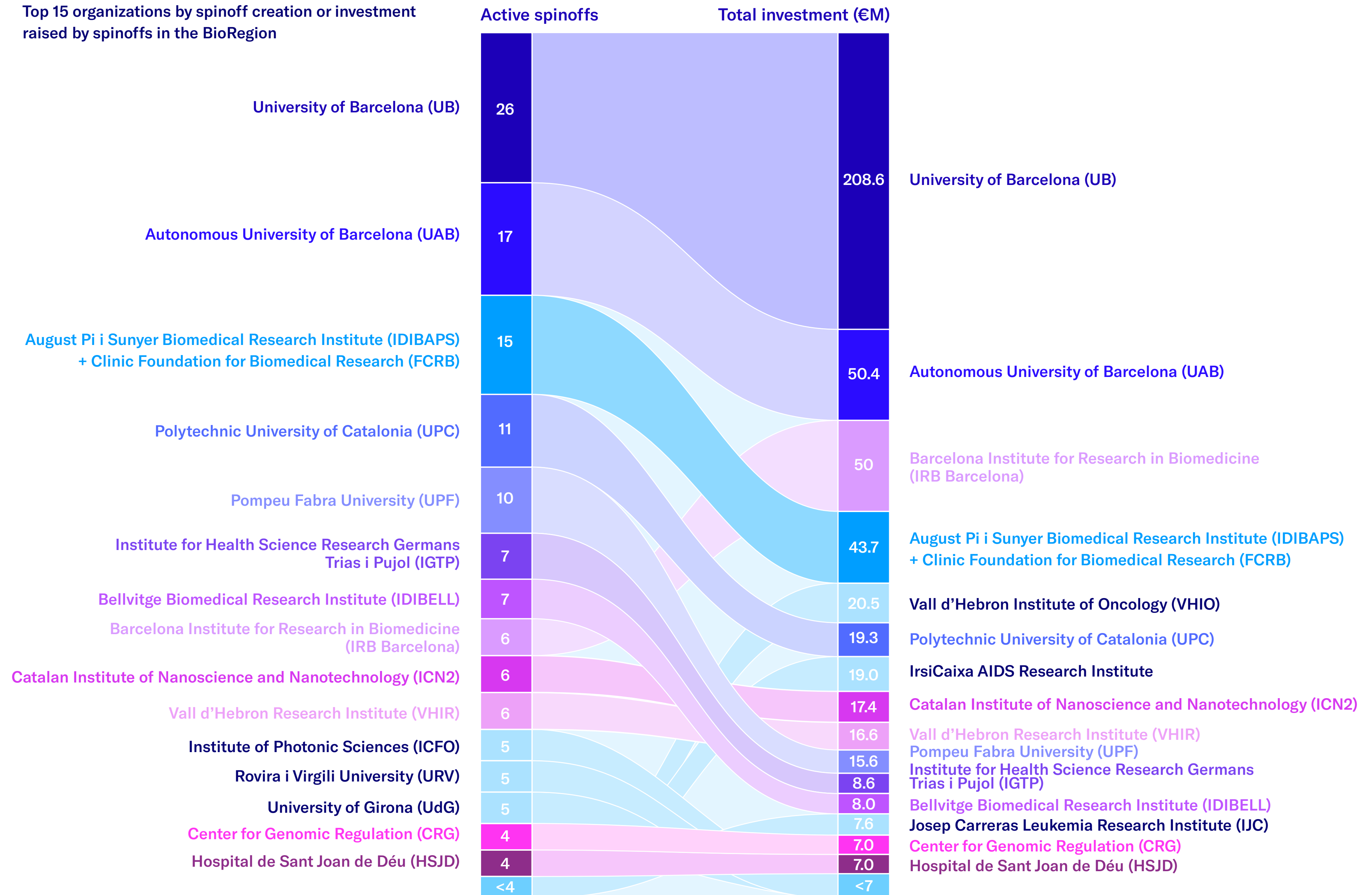
In terms of the relationship between company creation and investment raised, the UB stands out above the other universities. However, it is the spinoffs from research institutes that, in relative values, have a higher ratio of investment.

In this regard, it is worth highlighting the 24 spinoffs in the life sciences with an ICREA researcher, which received a joint total of €184M in 2021, up 50% from the previous year (€120M).

1 in 4 startups in the BioRegion is a spinoff



## Top 15 organizations by spinoff creation or investment raised by spinoffs in the BioRegion



Source: Biocat  
 Note: Spinoff creation (active in life sciences) and investment raised YTD by spinoffs in the BioRegion



# +200 digital health startups in the BioRegion

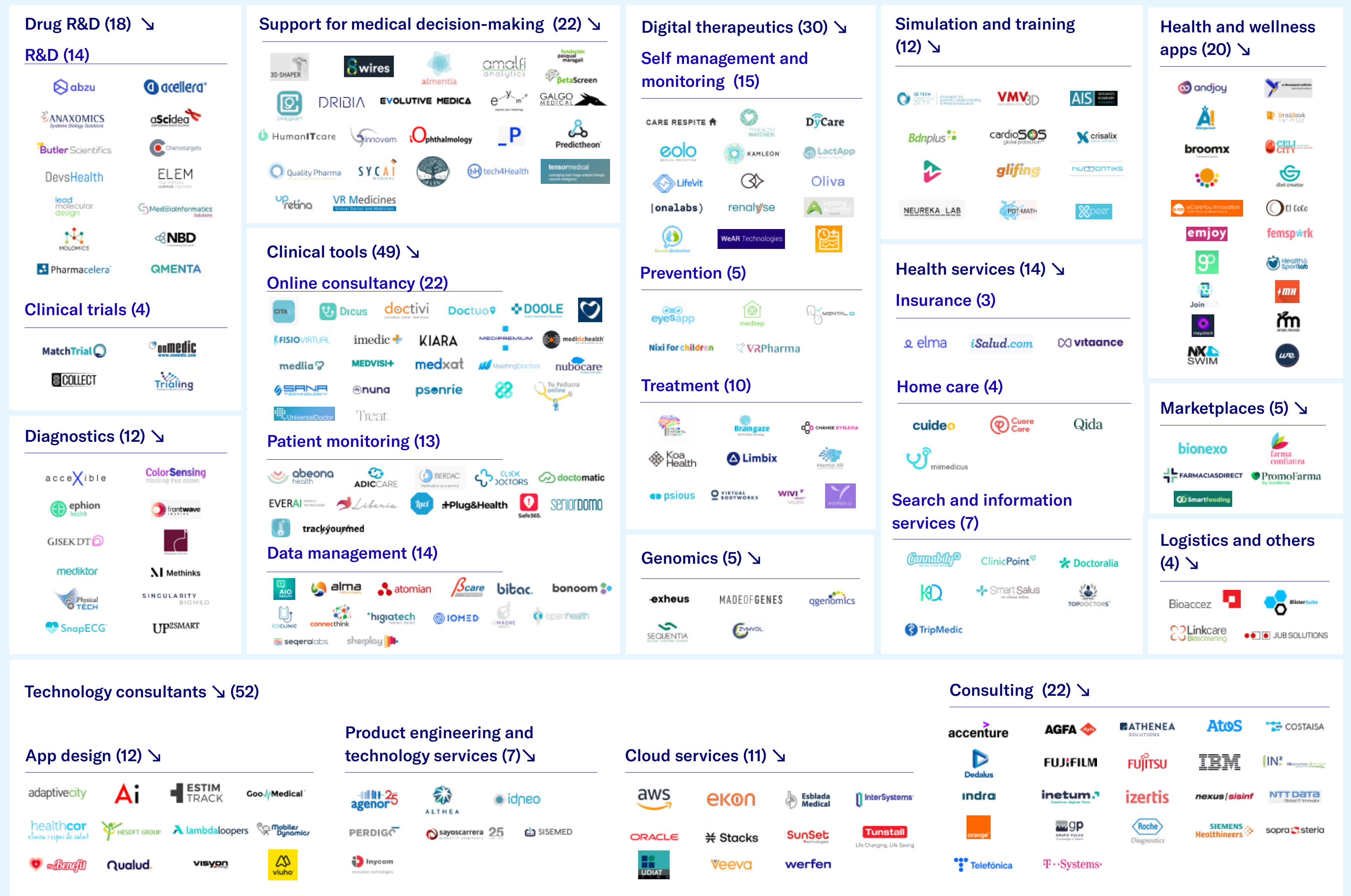
Digital health companies have played a key role during the COVID-19 pandemic, which has accelerated the use of technology, devices, apps, software and digital protocols in the system and by healthcare professionals.

The areas with the most companies in this subsector in the BioRegion are tools for clinical telemedicine, digital therapeutics, supporting medical decision-making and health and wellness apps.

It is a young, growing subsector, the smallest in terms of venture capital raised, but it hasn't stopped growing since 2017 and has nearly doubled in the past year, raising €60M in 2021.

These companies are an important catalyst for innovation and have great potential to turn new scientific discoveries into solutions for patients. In this regard, products regulated as digital therapeutics (DTx) stand out, as they show scientific evidence for treating and managing diseases, and have a direct impact on people's health. In Catalonia, there are 30 companies in this category.

## Map of digital health in the BioRegion



Note: This map is not exhaustive. The companies are featured by their main area of interest, but they could be classified into more categories.

Source: Biocat



# Deeptech companies working in healthcare-transforming technologies in Catalonia

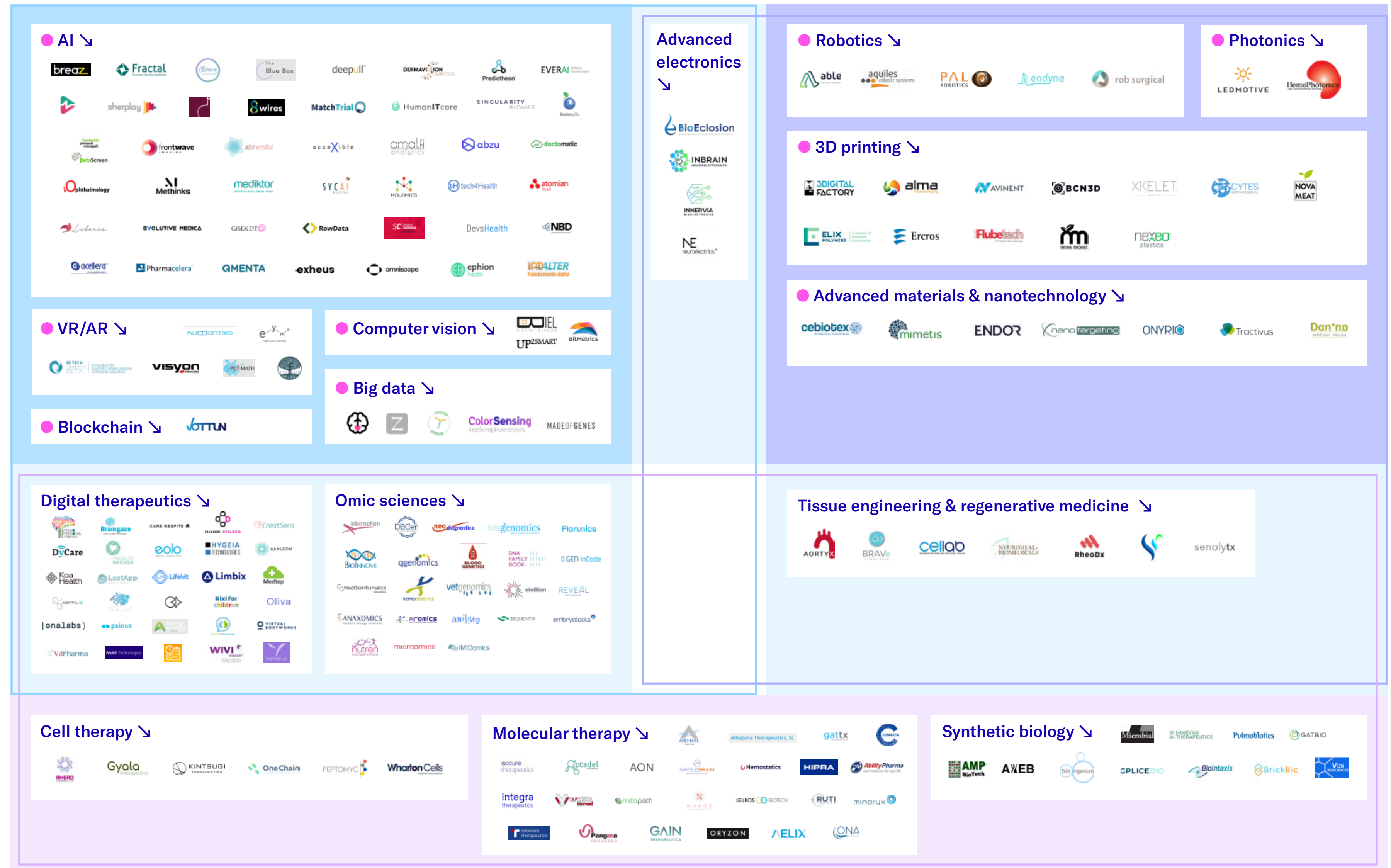
The accelerated pace of development for new technologies like artificial intelligence (AI), omics, 3D printing and virtual reality (VR) is fueling the ecosystem's growth.

The BioRegion has many companies and organizations developing and using these type of technologies to analyze and interpret huge amounts of data, regenerate cell functions, train healthcare professionals and create artificial tissue and organs, among others. All together, they will have a significant impact on how healthcare is provided and, therefore, on making the population healthier.

Furthermore, with the transformation that comes with Industry 4.0, companies are revolutionizing how their products are manufactured, connected and distributed to the market.

Map of companies working in healthcare-transforming technologies in Catalonia

■ Digital & Advanced Computer Sciences ■ Materials Science & Engineering ■ Biotechnology ■ Industry 4.0



Note: This map is not exhaustive. The companies are featured by their main technology of interest, but they could be classified into more categories.

Source: Biocat



02

## Investment and funding



This analysis looked at all the startups established in the BioRegion. The term 'startup' is used to refer to innovative, young, emerging companies that have received investment, competitive funding or venture capital in the early or later stages. See the Methodology section for more information.

# New record investment in startups with €238M

Investment in startups in the BioRegion remains unstoppable and again surpassed the €200M mark for the second year in a row, with venture capital (VC) as the unquestionable star in terms of funding.

Specifically, VC topped €180M in 2021, growing to 79% of the total capital raised by emerging companies, concentrated in fewer rounds (36) than in 2020. This means there weren't as many rounds but each operation was bigger in volume.

The decrease in competitive funds received through public calls in 2021 diminished the (to date) second largest source of funding for startups in the BioRegion (grants).

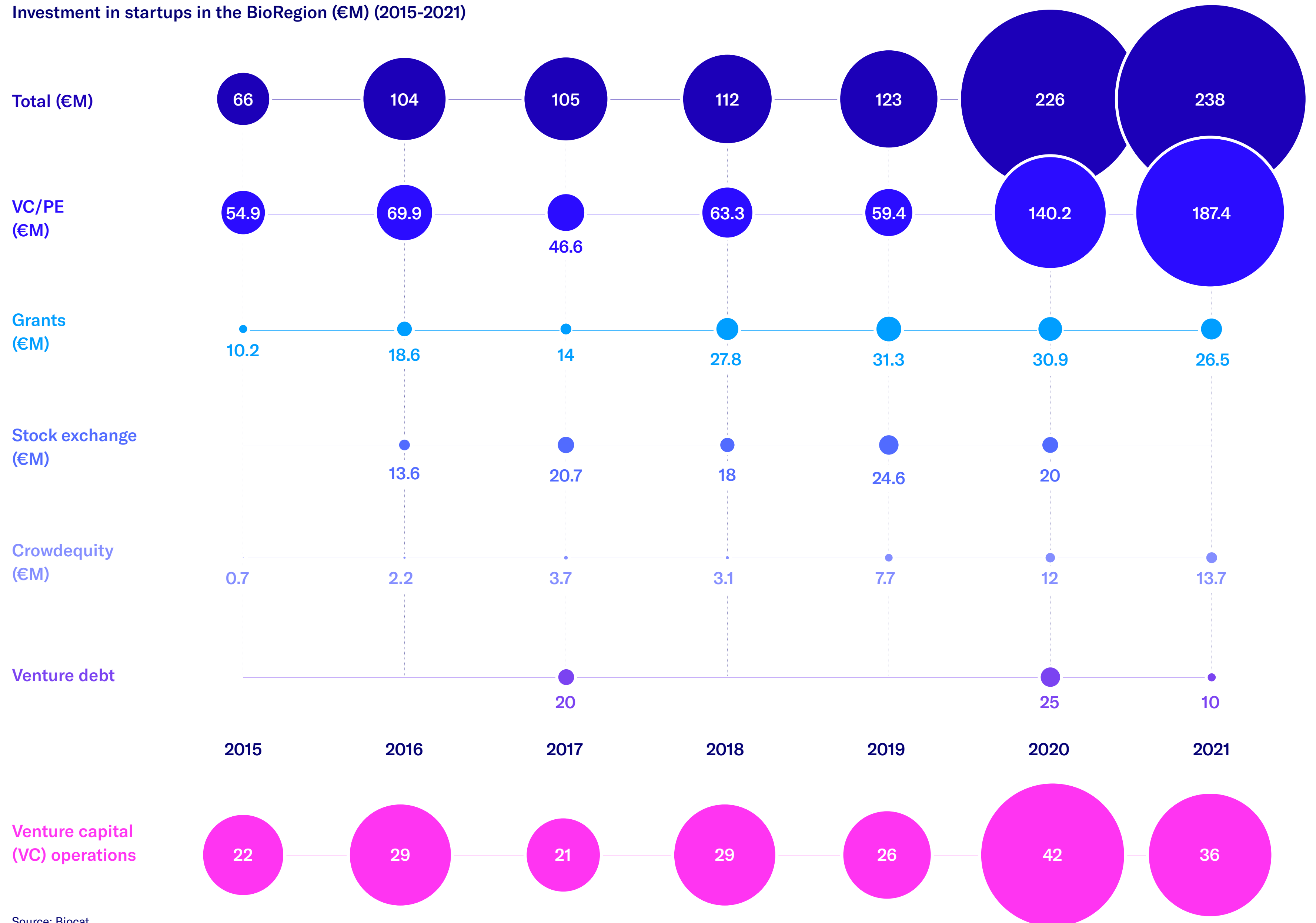
Investment channeled through crowdequity platforms continues to stand out, growing every year: It has multiplied x3.7 since 2017 and is now over €13M. One of the top platforms in Europe, which led most of these operations, is Capital Cell, which has its main headquarters in Barcelona.

Note: This investment includes capital raised by startups in Catalonia in the biopharmaceutical, medtech, digital health and R&D services subsectors. It also includes investment in startups working for the life sciences sector as suppliers or engineering and professional services firms.

VC/PE: venture capital / private equity

Venture debt: Venture debt: only funding for startups from the European Investment Bank (EIB)

Investment in startups in the BioRegion (€M) (2015-2021)



Source: Biocat



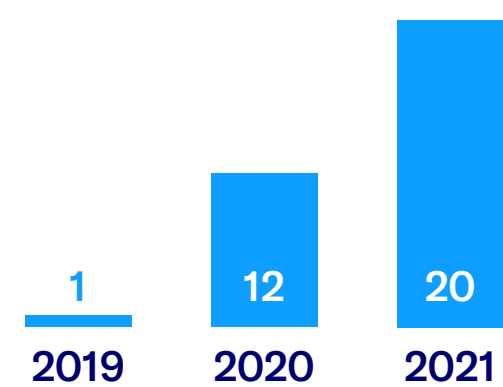
# Investment in medtech and digital health, on the rise

After a year in which biotech companies saw greater investment than in other periods and subsectors thanks to three important rounds, 2021 stands out for the growth in investment in medical technology and digital health.

Medtech companies have attracted more investment at a steady rate since 2018, up a noteworthy 76% from 2020.

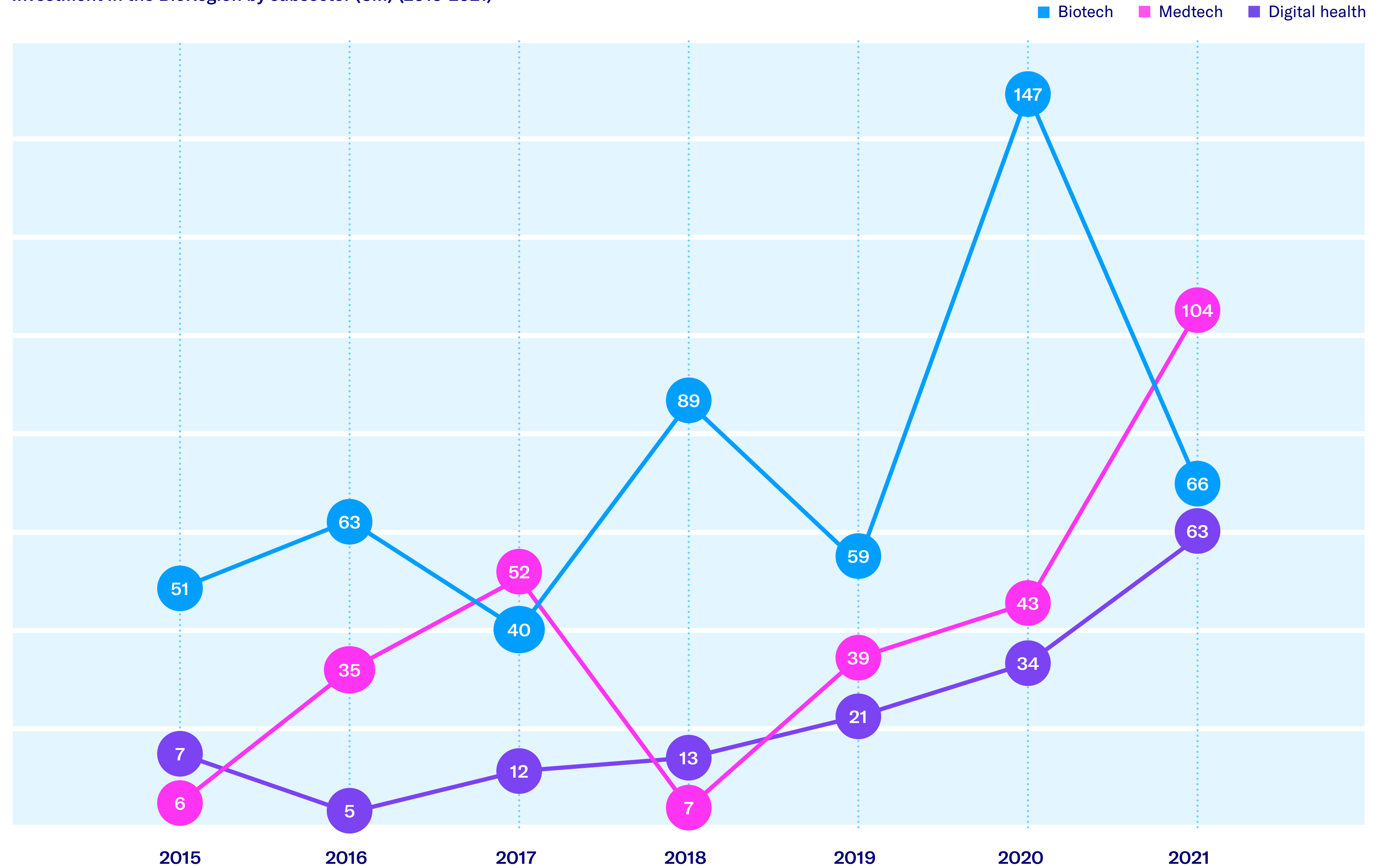
Furthermore, digital health companies have seen nearly twice as much investment, consolidating the increase in funds raised for the fifth year in a row. The boom in this subsector is a global trend that has been accentuated during the pandemic due to the use of telemedicine. Wearables to monitor health, and mental health and women's health apps, plus digital therapeutics, are driving the momentum in this segment.

The graph below shows how diagnostics startups in the BioRegion have also caught the interest of investors during the pandemic.



↗ VC investment (€M) in diagnostics startups (molecular, *in vitro*, medical devices and digital)

Investment in the BioRegion by subsector (€M) (2015-2021)



Source: Biocat

Note: Investment in biotechnology includes therapeutics companies, R&D services and others that impact human health

# The scale up of success stories

Startups in the BioRegion of Catalonia attract more investment each year. This chart shows the companies that have raised over €3M in recent years, reflecting the positive evolution in terms of the level of funding achieved.

The two most important rounds of the year were completed by companies in the medtech subsector, both working in dental health: Impress, with €41M (the largest round so far in the history of the BioRegion) and Corus Dental, with €25M.

It is worth noting that over 90% of operations over €10M are syndicated and include international investors.

Beyond the main rounds, it is also worth noting that 20 startups have raised between €1M and €3M, ensuring a good foundation of projects with potential to scale up in the coming years.

## €1-3M 2021



Source: Biocat

\* The funds received by Corus Dental from the VC firm Careventures totaled €50M (50% capital and 50% debt)

	2018	2019	2020	2021
+€40M				Impress
€20-40M	minorix therapeutics	ANACONDA BRAIN ADVANCED THROUGHBRAIN™ SYSTEM	QONA minorix therapeutics	Corus
€10-20M	ABAC Therapeutics		NE neuroelectronics® Koa Health AbilityPharma real medicine for real life PEPTOMYC	Koa Health INBRAIN NEUROELECTRONICS IMIDomics mediktor ARTIFICIAL INTELLIGENCE TRIAGE TOPDOCTORS™ VEnvirotech ANACONDA BRAIN ADVANCED THROUGHBRAIN™ SYSTEM
€5-10M		SOM BIOTECH psious rob surgical	accure therapeutics NEOS FUSION oxolife Impress	abzu SEQUENTIA DECODE • DISCOVER • DISRUPT
€3-5M	mediQuo bionure Biomedicine heading to future mediktor ARTIFICIAL INTELLIGENCE TRIAGE	elma AbilityPharma real medicine for real life	miwendo SOLUTIONS ADmit THERAPEUTICS Qida deepull™ GENinCode OneChain IMMUNOTHERAPEUTICS elma CONNECTA	BOKA DABA seqeralabs Integra therapeutics AORTYX NUAGE THERAPEUTICS vitaance

Source: Biocat



# Mergers, acquisitions and initial public offerings (M&A and IPOs)

## Business exits in the BioRegion (2015-2020)

Year	Target	Buyer
2021	bioinfogate advancing data science for health	>  Clarivate™ (US)
	DDR Drug Development & Regulation	>  VERISTAT (US)
	DR CARE Innovating in DAO Deficiency A business unit of AB Biotek	>  ABBiotek A business division of AB Biotek
	GOODGUT Enhancing digestive health	>  HIPRA (ES)
	ininitec Innovative Biotechnology	>  EVONIK POWER TO CREATE (DE)
	Vcn Vaccines	>  Synthetic Biologics (US)
2020	Palex Constant Improvement	>  ERGO CAPITAL (ES)
	COOVACUUM Technologies	>  Dara Pharmaceutical Packaging (ES)
2019	AB-BIOTICS	>  Kaneka (JP)
	pensa	>  TOWA PHARMACEUTICAL (JP)
2018	advance medical	>  Teladoc HEALTH (EUA)
	EUROMED	>  Dermopharm Holding SE (DE)
	iSalud.com	>  CNP PARTNERS (ES)
	PromoFarma.com	>  R (CH)
	STAT Dx Closer to Care	>  QIAGEN (NL)
	GAES	>  amplifon (IT)
2016	QM Quintiles Medical	>  FRESENIUS KABI caring for life (DE)
	Doctoralia	>  Docplanner (PL)
	Mosai Biomedicals	>  NORTHERN BIOLOGICS (CA)

Source: Biocat

2021 stood out for its significant number of M&A operations.

The biotech firm GoodGut, a spinoff of UdG and IDIBGI that focuses on digestive diseases, was acquired by pharmaceutical multinational corporation HIPRA (a case of successful technology transfer). HIPRA, based in Girona, is the sixth largest manufacturer of animal vaccines in the world. With this operation, the pharmaceutical corporation has reinforced its human health division, which has been in the news during the pandemic for its recombinant protein vaccine that is currently in phase III.

AB Biotek, a division of Associated British Foods (a British multinational corporation specializing in probiotic strains), acquired biomedical company DR Healthcare, bringing into its sales portfolio DAO, an enzyme the company will harness for human health and nutrition solutions.

In scientific information, Bioinfogate, an artificial intelligence platform for translational drug safety and toxicity belonging to the Prous family, was acquired by US giant Clarivate Analytics. The operation puts the multinational corporation, which has hallmark biopharmaceutical products like Web of Science, EndNote and ScholarOne, in a place to compete as a benchmark in toxicology of new drugs. This is the second operation the group has carried out with the Prous family, which in 2007 sold Prous Science to Thomson Reuters, which was later also acquired by Clarivate.

In mid-2021, German multinational corporation Evonik announced a new investment in Spain through the acquisition of the biotech firm Ininitec Activos, which specializes in developing active ingredients for the cosmetics industry. The year drew to a close with the news that Grifols had sold its stake in oncology startup VCN Biosciences to US company Synthetic Biologics for €66M.

Another highlight of the year was Docplanner, which acquired Doctoralia in 2016 and became one of the latest European unicorns in the healthcare sector in 2021, joining the other five already in the EU. Since 2018, the number of unicorns in Europe has tripled and their valuation has increased six-fold.

Eight European unicorns also went public, through IPOs or SPACs. The gap with the United States, however, is still huge, as reflected on the next page of this Report.

## Companies traded on the stock market

Company	IPO	Exchange	BME Growth <sup>1</sup>
Grifols <sup>2</sup>	2006	●	-
Almirall <sup>2</sup>	2007	●	-
AB Biotics <sup>4</sup>	2011	-	●
Inkemia <sup>3 4</sup>	2012	-	●
Reig Jofre	2015	●	-
Oryzon <sup>3</sup>	2015	●	-
Pangea Oncology <sup>3</sup>	2016	-	●

<sup>1</sup> Formerly MAB (Alternative Equity Market)<sup>2</sup> Traded on the IBEX 35<sup>3</sup> Moved official company headquarters but maintained activity in Catalonia<sup>4</sup> Stopped trading on MAB (now BME Growth) in 2019

# Stock markets as an alternative source of funding for startups

In recent years, we've seen how some Catalan biotech companies have used the stock market as a source of funding in addition to venture capital. Specifically, two startups went public between 2015 and 2020: Oryzon and Pangea Oncology.

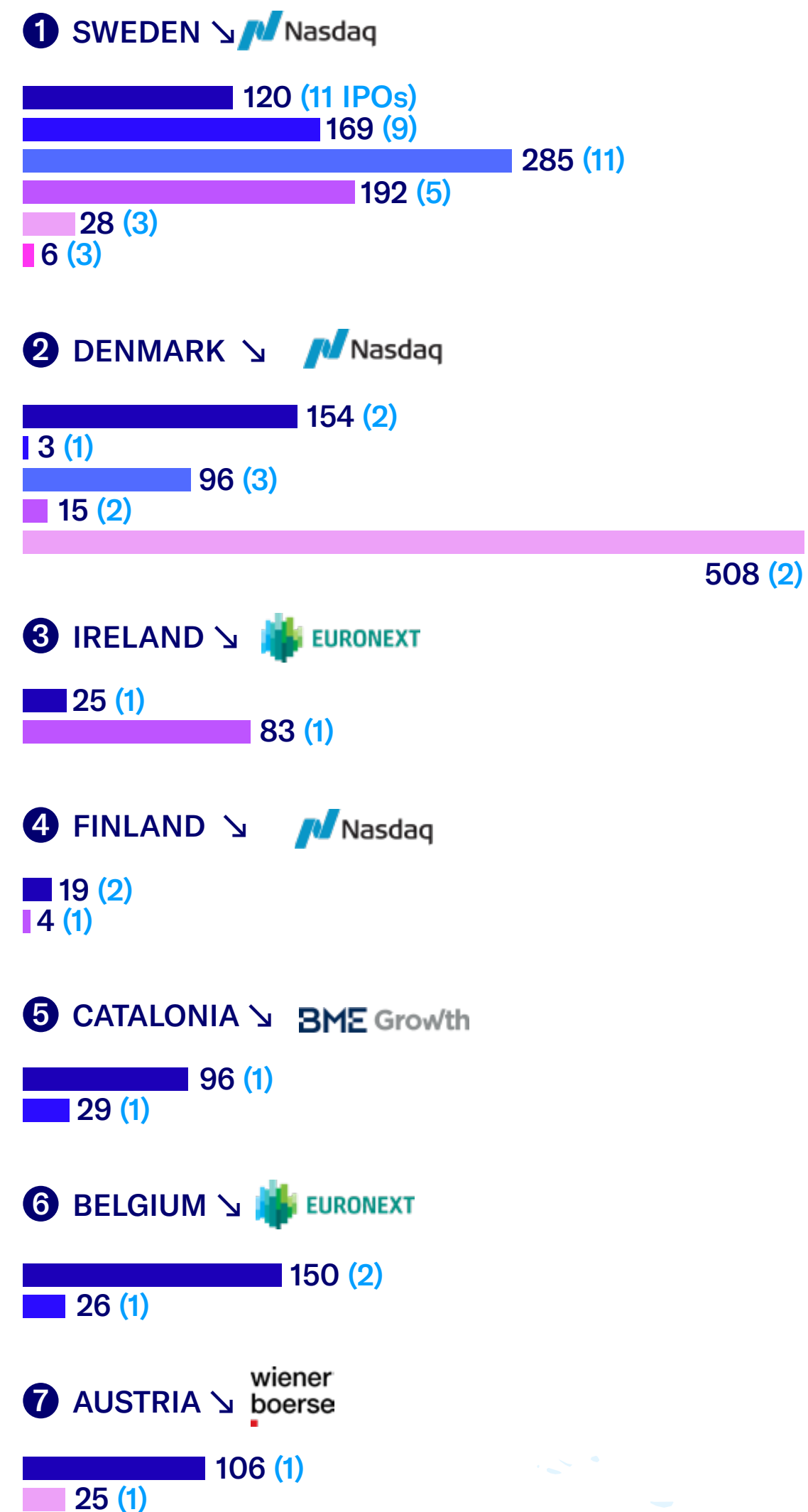
Previously, AB-Biotics had launched an IPO in 2010 and was publicly traded for nine years until its new owner, Kaneka, made a corporate decision to stop trading.

With an international view, the IPO figures for biotech companies in Catalonia are similar to comparable European countries like Finland, Ireland, Belgium and Austria. All of them have had no more than 3 IPOs since 2015, with cumulative funding under €200M. Sweden and Denmark have more dynamic markets in terms of number of operations and capital raised.

There haven't been any IPOs by Catalan companies in the medtech sector yet, and the same is true for Austria and Ireland. The Swedish stock market once again stands out for its pull.

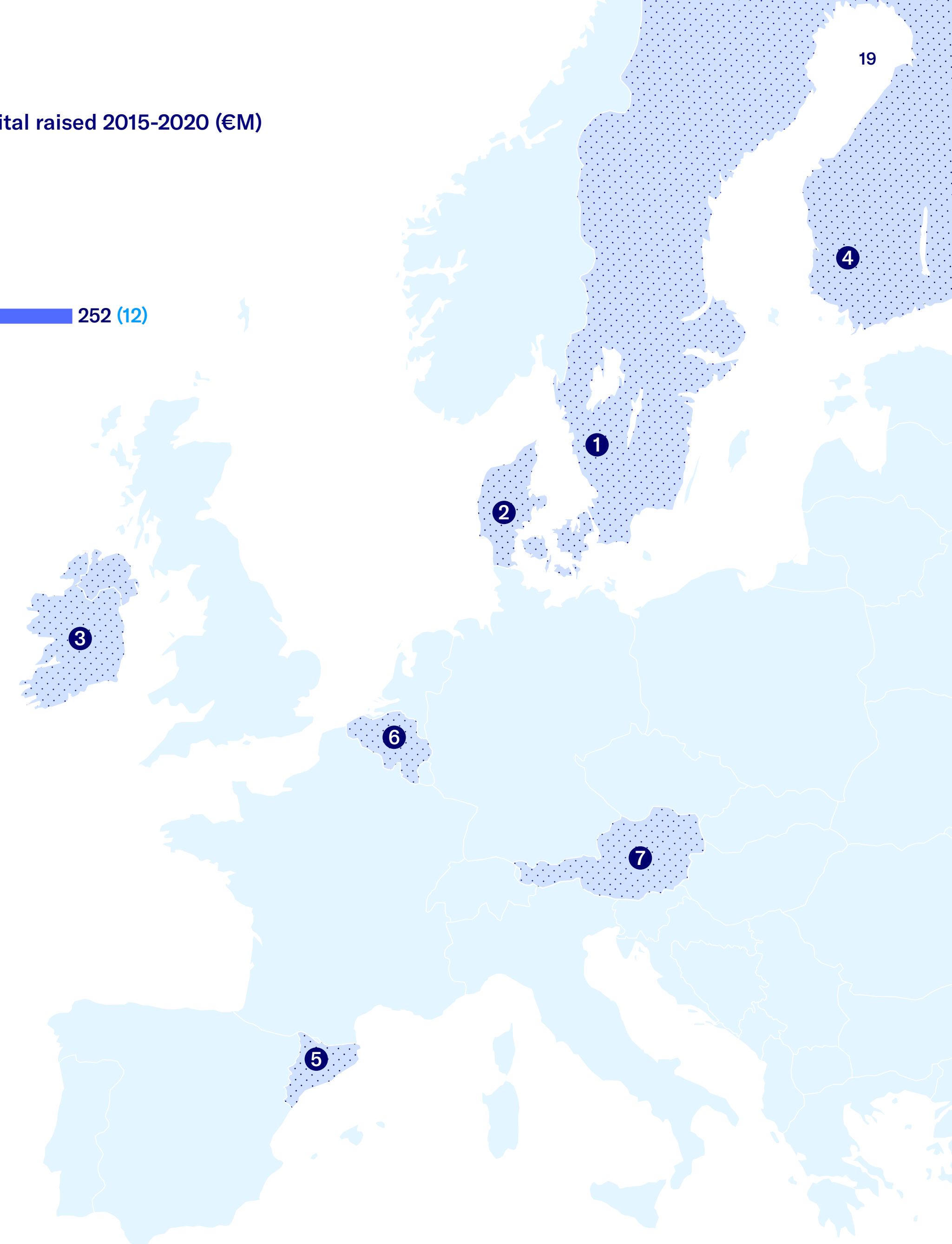
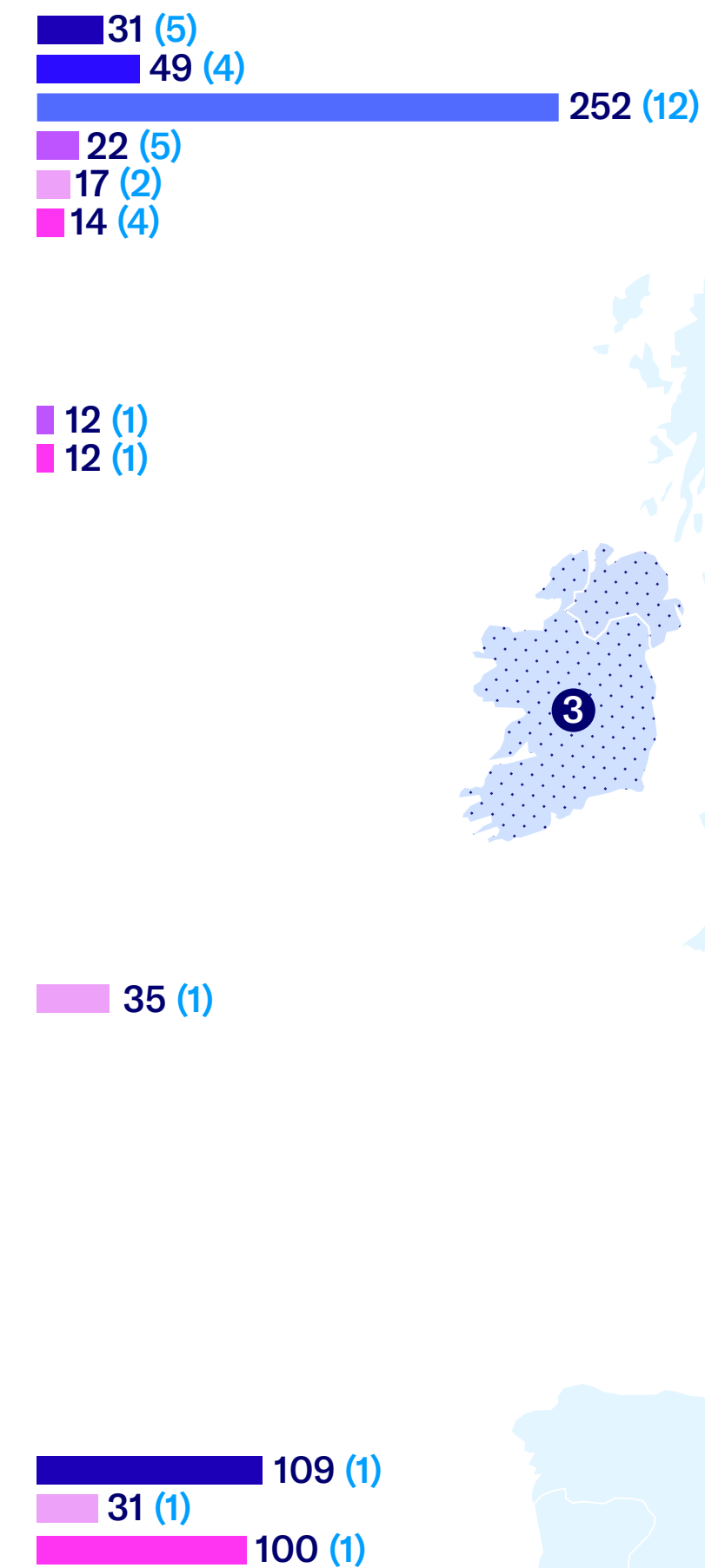
Hopefully as the sector matures in Catalonia stock markets will become an attractive alternative for funding beyond VC, as has happened in Sweden and Denmark.

Evolution of IPO capital raised 2015-2020 (€M)  
Biotech



Source: EY

Evolution of IPO capital raised 2015-2020 (€M)  
Medtech



Legend for years: 2015 (dark blue), 2016 (blue), 2017 (light blue), 2018 (purple), 2019 (pink), 2020 (magenta)



# Most venture capital operations count on international participation

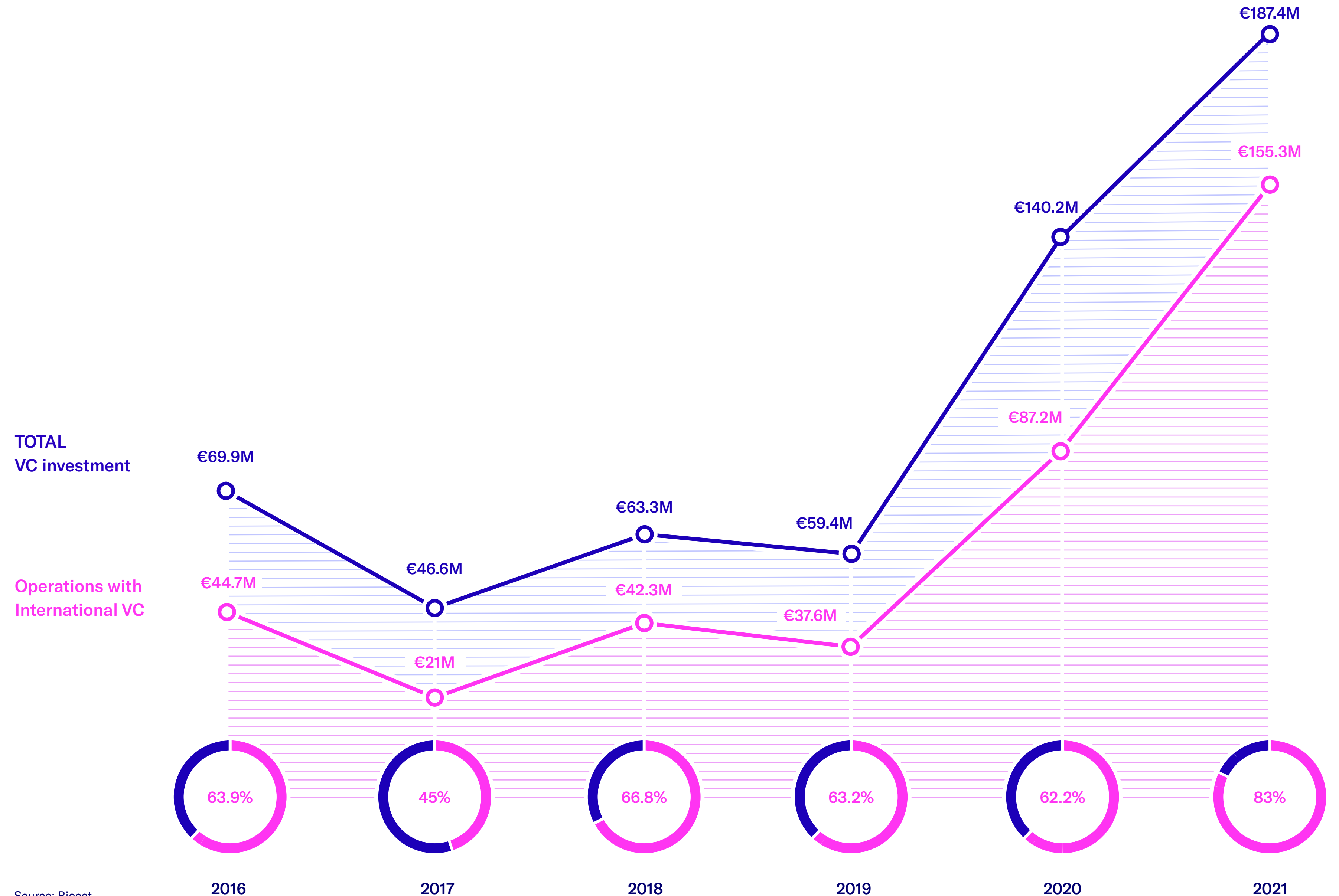
Joint operations with international and Catalonia-based investors continue to grow in number and size. In 2021, venture capital tripled from 2019, driven by the international participation in operations, which was four times higher than that year's.

83% of venture capital raised comes from operations that include international participation. In fact, more than 90% of operations over €10M are syndicated with international investors, which is above the European average.

It is also noteworthy that 77% of VC investment was concentrated in 8 large rounds (>€10M) with a total of €144M.

This trend is consolidating the BioRegion as a hub for attracting international capital, and highlights the competitiveness of the science and startups here, as well as the intense collaboration activity and pull of investors established in Barcelona.

Evolution of VC investment (2016-2021)



Source: Biocat

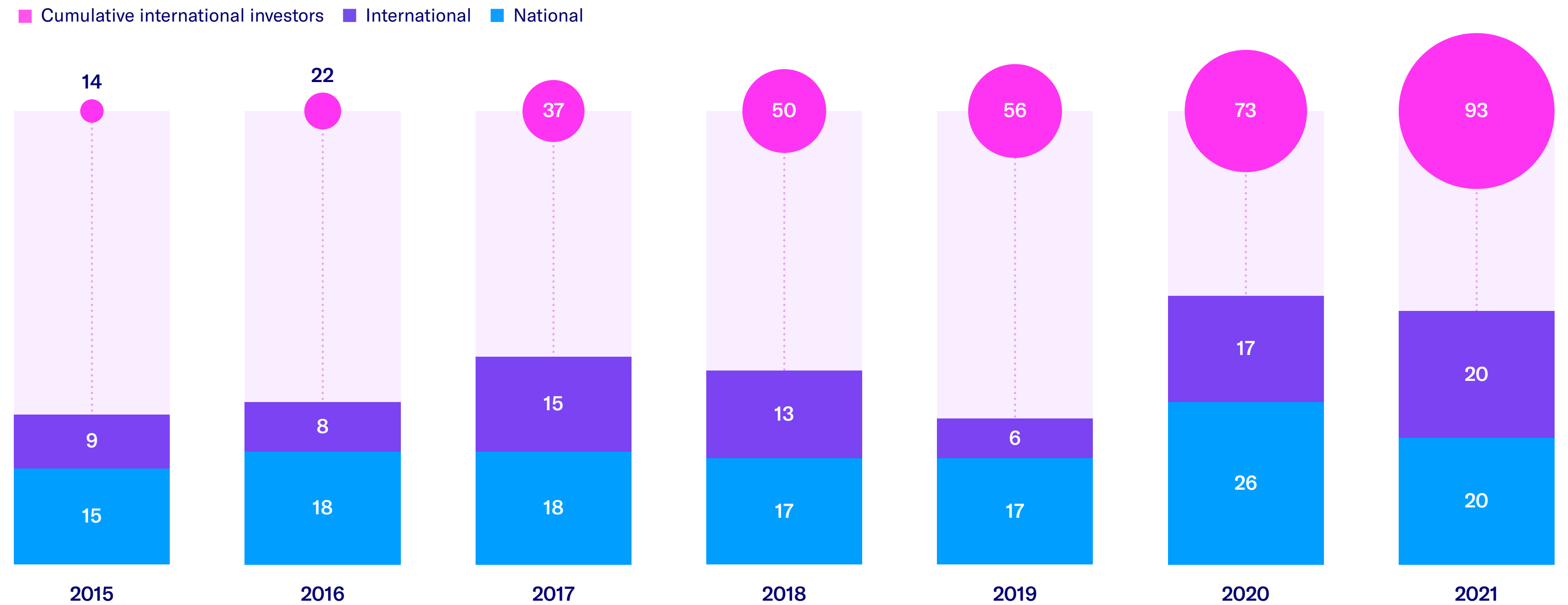
# Main international investors in the BioRegion

As we saw on the previous page, 2021 was a record year in terms of attracting international investment to the BioRegion.

This graph shows the evolution of international participation in rounds of investment in startups, most of which is from the United States, United Kingdom and the rest of Europe.

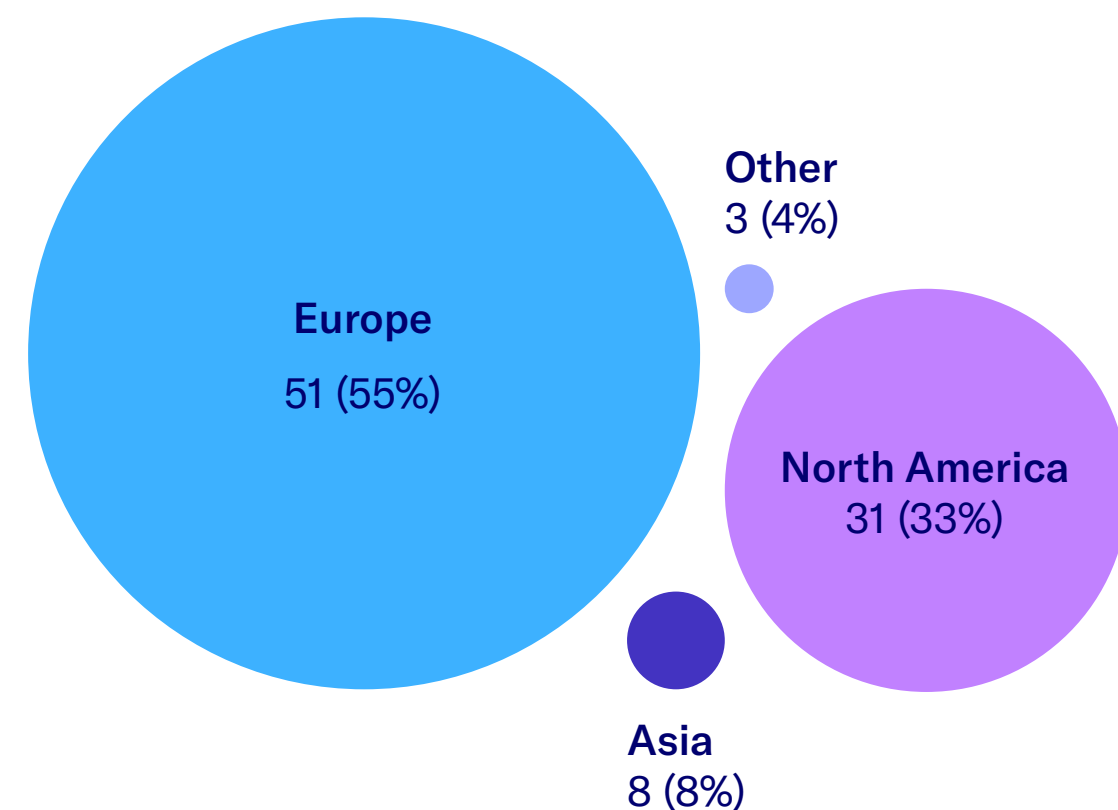
In three years, the number of international firms that have invested in the BioRegion has nearly doubled and is now close to one hundred.

Number of international investors in life sciences and healthcare startups in the BioRegion



Source: Biocat

## Geographic breakdown ↘



## Noteworthy international investors ↘



## International investors 2021 ↘





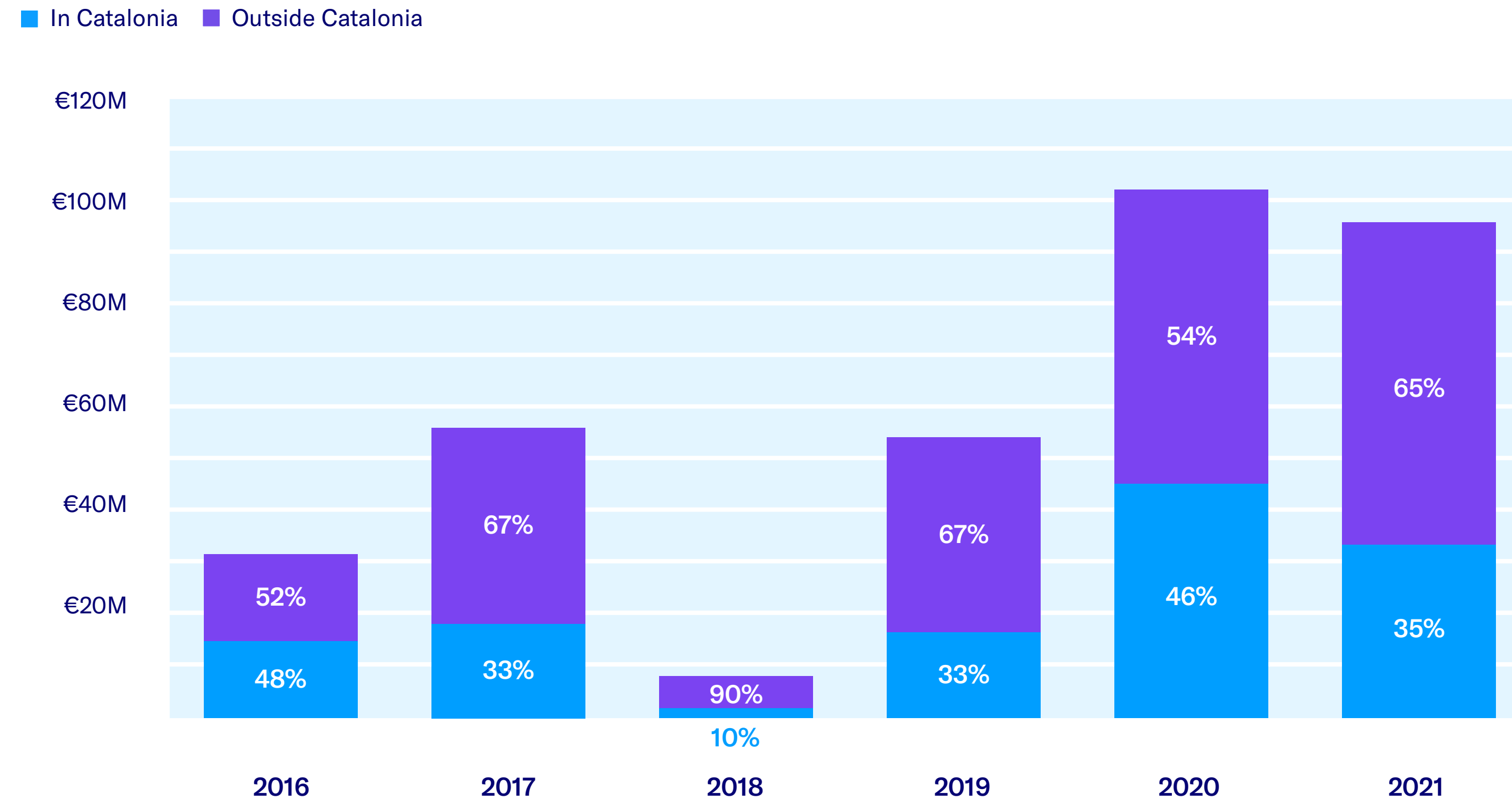
# VCs established in Catalonia consolidate activity

Apart from a good number of international investors, the BioRegion also has a solid group of specialized investment funds, some of which actively invest in startups in the BioRegion, including Alta LS, Asabys Partners, Caixa Capital Risc, CG Health Ventures, Inveready, Invivo, Nina Capital, Ysios Capital and the Capital Cell crowdequity platform.

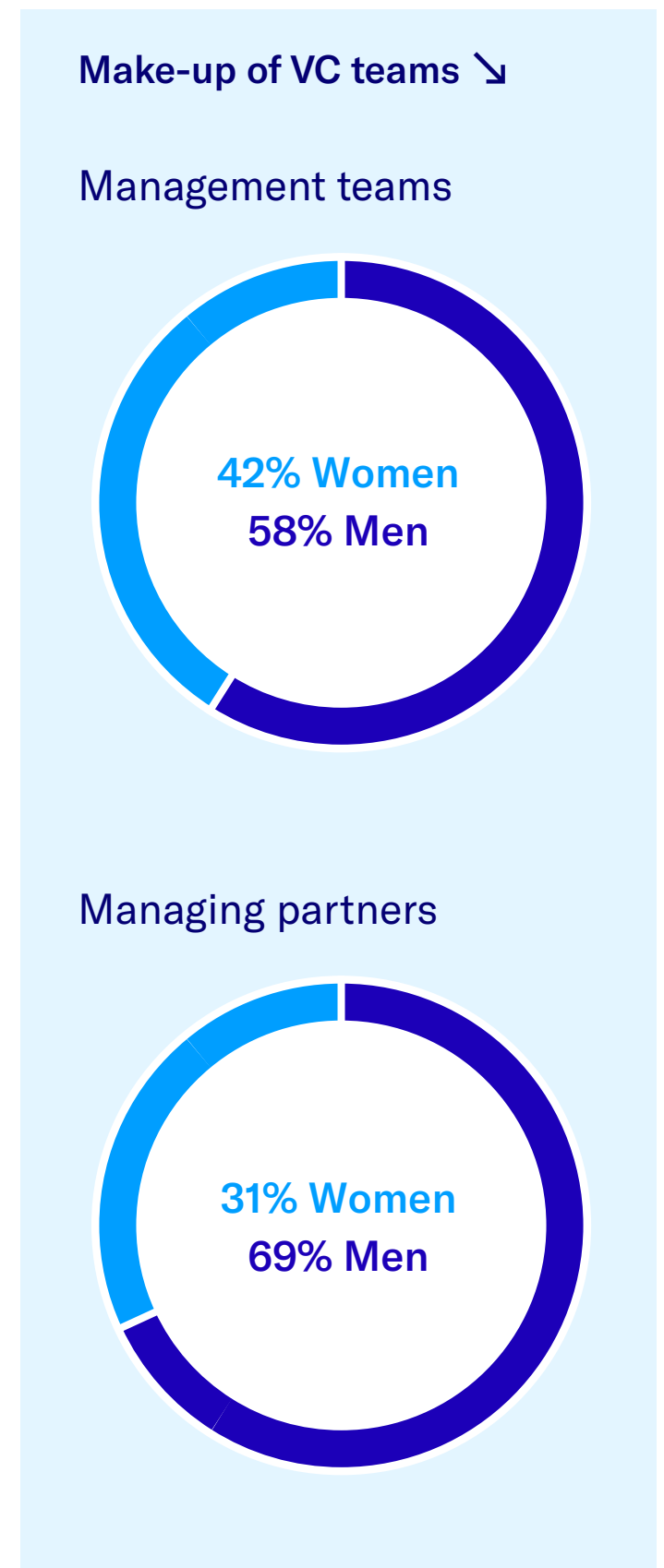
In 2020, these funds committed over €100M of capital and the figure for 2021 is similar. The average percentage of capital committed annually in Catalonia makes up 40% of the total. The drop in 2018 coincided with the fundraising stage for some of the VCs, which has allowed them to make new investments the following years.

Furthermore, investors from the BioRegion show noteworthy awareness of diversity and sustainability, as can be seen in the recognitions granted to Ysios (Diversity VC) and Asabys (Bureau Veritas). In terms of gender diversity, the figures for management teams and managing partners are better than the average for VC/PE in any other sector in Spain, according to a study published by Nina Capital and Level 20 (September 2021).

## Capital committed by VCs established in the BioRegion



Source: CataloniaBio & HealthTech



## Main specialized investors established in Catalonia





03

# Other insights\* on business activity



\*The insights in this chapter are taken from a survey of CataloniaBio & HealthTech members carried out in September 2021, which 87 companies in Catalonia took part in. The results were compiled and analyzed in collaboration with international consultancy EY.



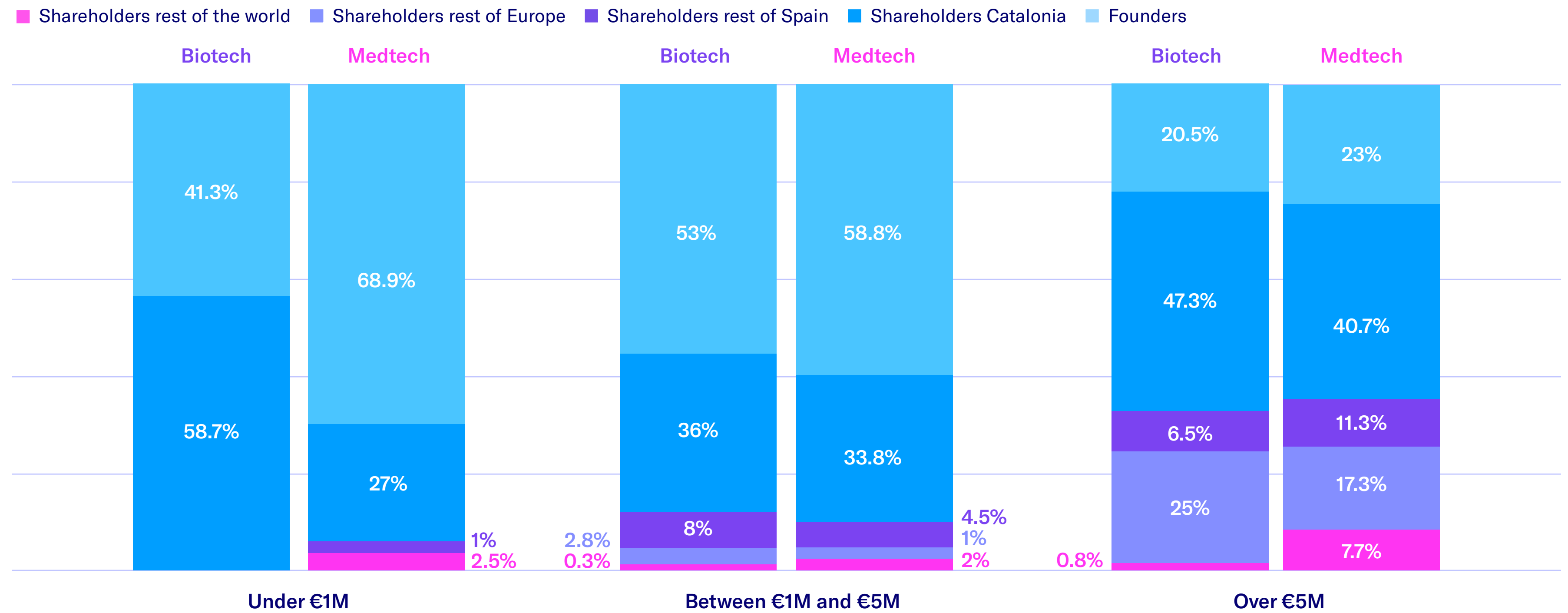
# Despite the variation in the origin of the capital raised, most shares stay in Catalonia

For both biotech and medtech startups, when the total capital raised is under €5M, most of the shares are held by the founders and other Catalan investors. As companies move into larger rounds, more international investors come on board, normally through syndicated investments.

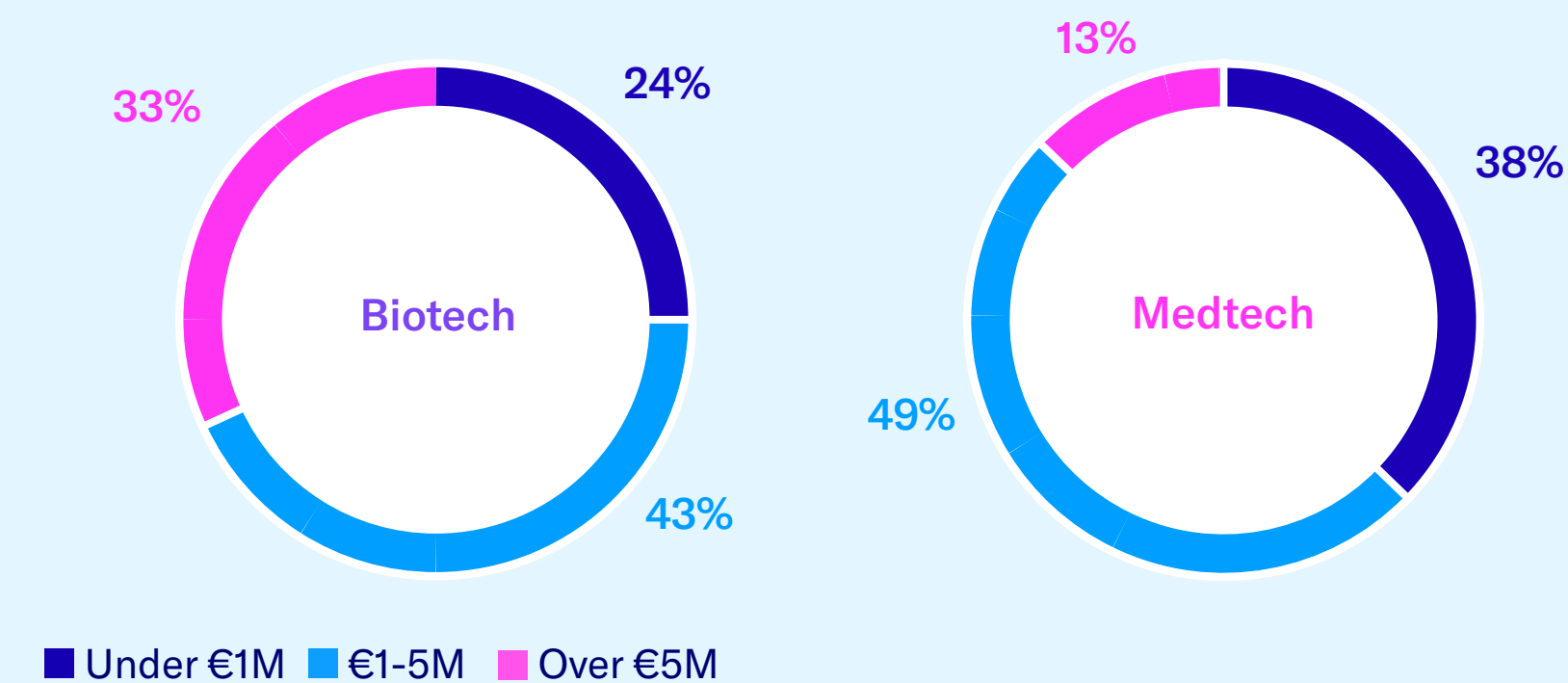
Another variable of note is the volume of funding raised over the life of the company. 33% of biotech startups and 13% of medtech startups have surpassed the €5M barrier.

As a whole, the breakdown of shares held by the investors' geographic origin has remained unchanged, with 75% of shares held by investors in Catalonia.

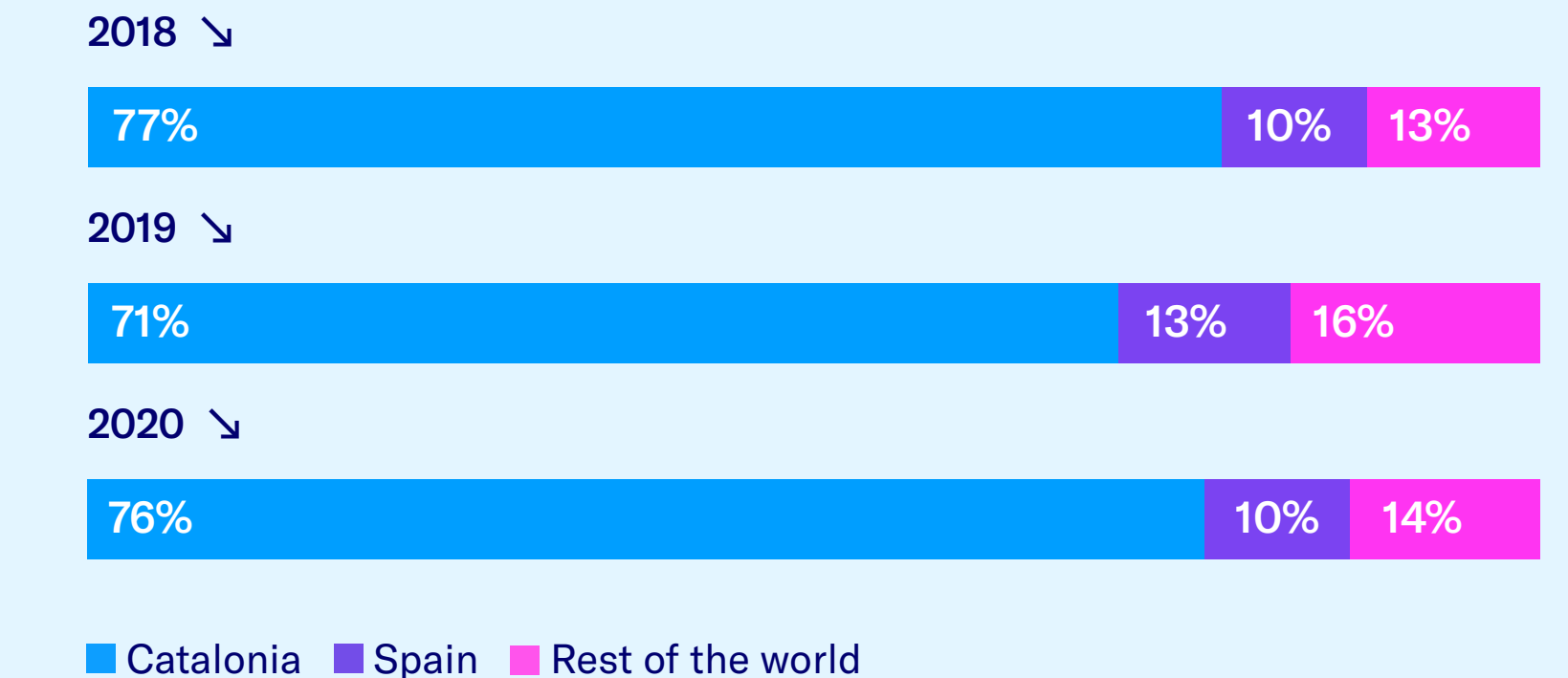
Funding raised by geographic origin of investors



% companies by level of funding



Evolution of geographic origin of investors (biotech + medtech)



Source: CataloniaBio & HealthTech and EY

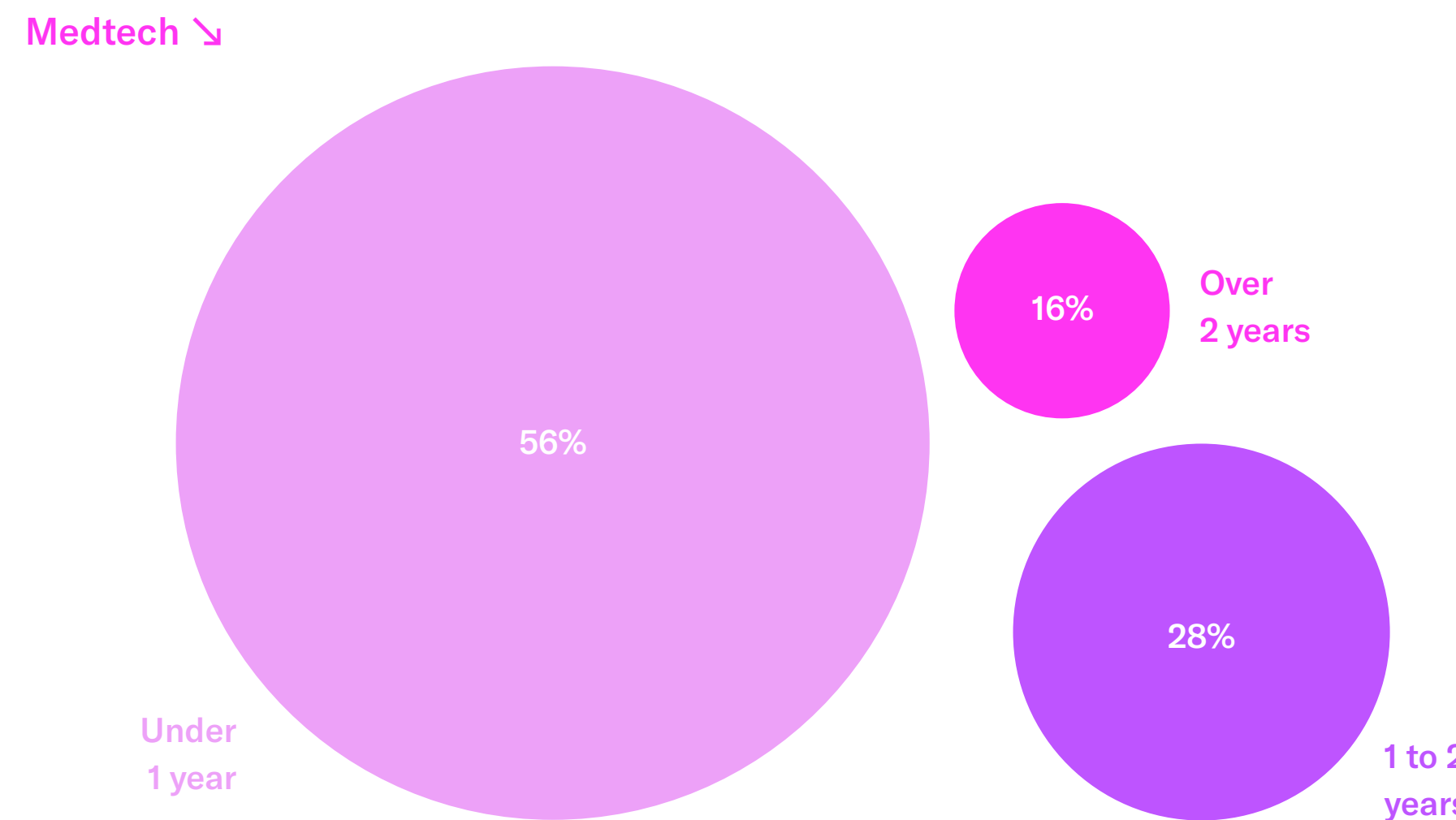
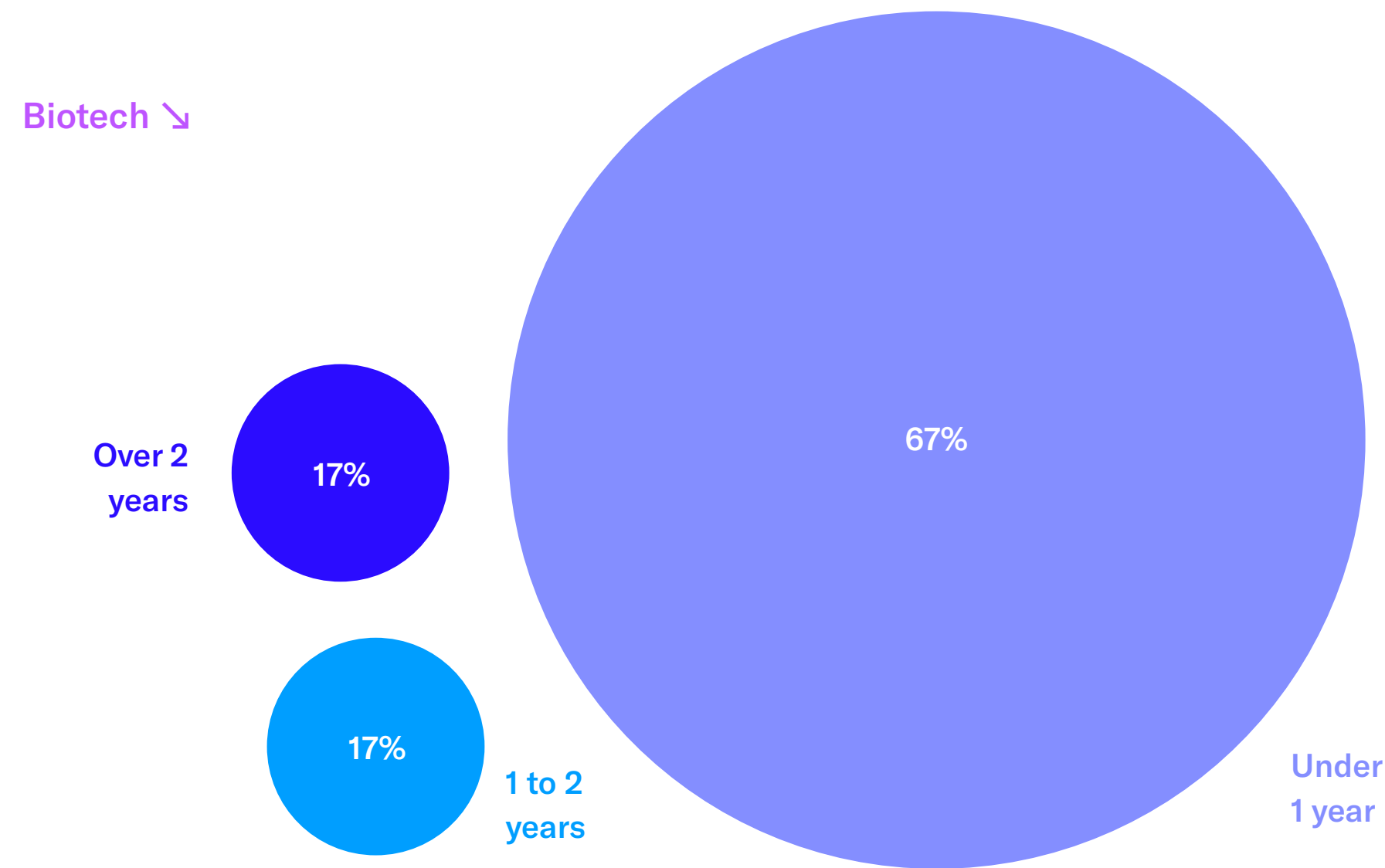
# Startups in the healthcare sector are capital-intensive. More than half of them will need more funding within the next 12 months

One key aspect that concerns entrepreneurs is knowing how long they can operate before they need more funding. For biotech companies, 67% said they have funds for less than one year from the time they were asked, while that percentage drops to 56% for medtech startups.

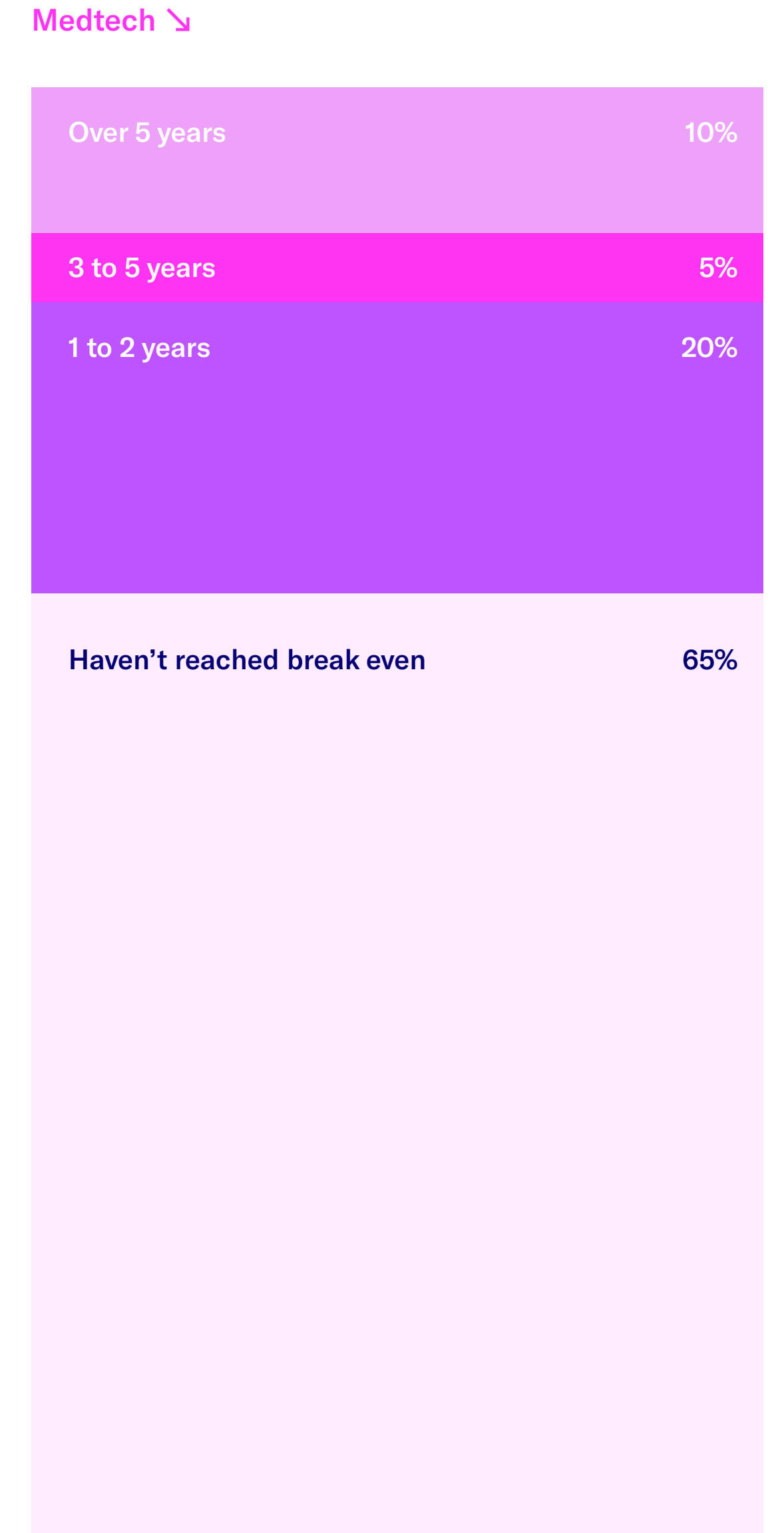
Reaching the market is the dominant business model for medtech startups, although 20% of them don't follow this pattern and say they don't plan to break even. This group is working with a model based on licensing their technology or selling the company. Of the former (80%), 35% have reached break even in 1-2 years (20%), 3-5 years (5%) or more than 5 years (10%).

These data shows that startups in the BioRegion are capital-intensive, a characteristic trait of the sector, and require several capital injections to complete R&D, build production capacity and scale up their business so their developments can reach patients.

Breakdown of companies by time they can operate with funds available



Breakdown of medtech companies by time to break even



Source: CataloniaBio & HealthTech and EY



# The main destination of R&D investment by biotech and medtech companies is Catalonia

Companies in the BioRegion operate and compete on an international level, although the preferred destination for R&D investment by biotech and medtech startups (53% and 78%, respectively) is Catalonia. The data in this report reflect the entrepreneurial fabric's confidence in the research and development capacities of the BioRegion. In line with mature regional ecosystems in Europe, Catalonia has all the ingredients for startups to be successful: funding, talent and mentality, plus an ecosystem of partners that boosts the impact of their activities.

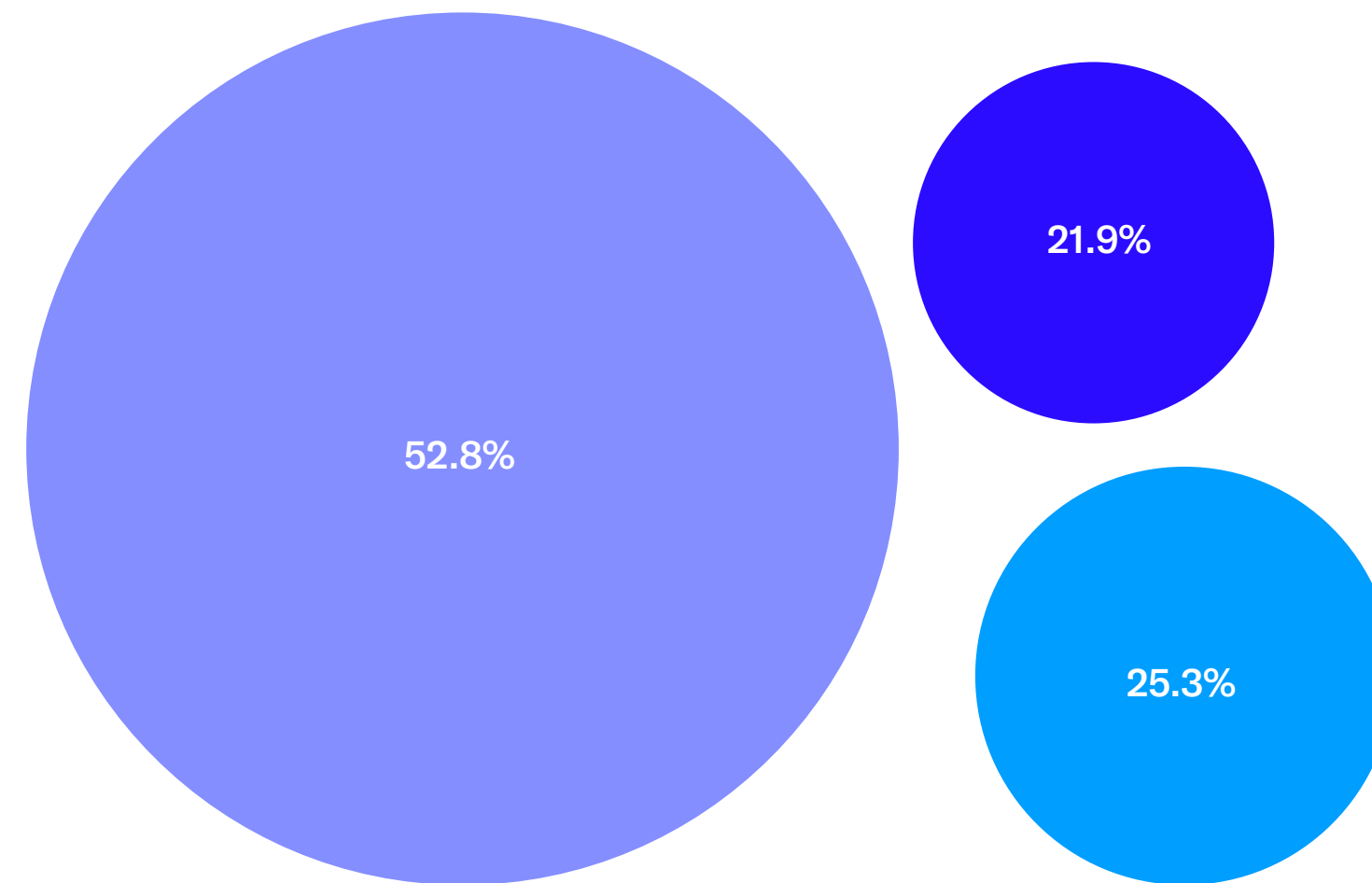
To a lesser degree, startups in the BioRegion also operate and compete outside the ecosystem, as reflected in the percentage of R&D investment in the rest of Spain and internationally, with roughly 22% for medtech and 47% for biotech firms.

Biotech companies devote a similar percentage of their investment (about 20%) to clinical and preclinical research and development activities, and less to regulatory affairs and IP. At medtech startups, 32% of investment goes to product development, which is their main activity, followed by research (21%). It is of note that they invest less in preclinical and clinical activity (28% of the total) and more in regulatory (19%) than biotech companies.

## Geographic breakdown of R&D investment

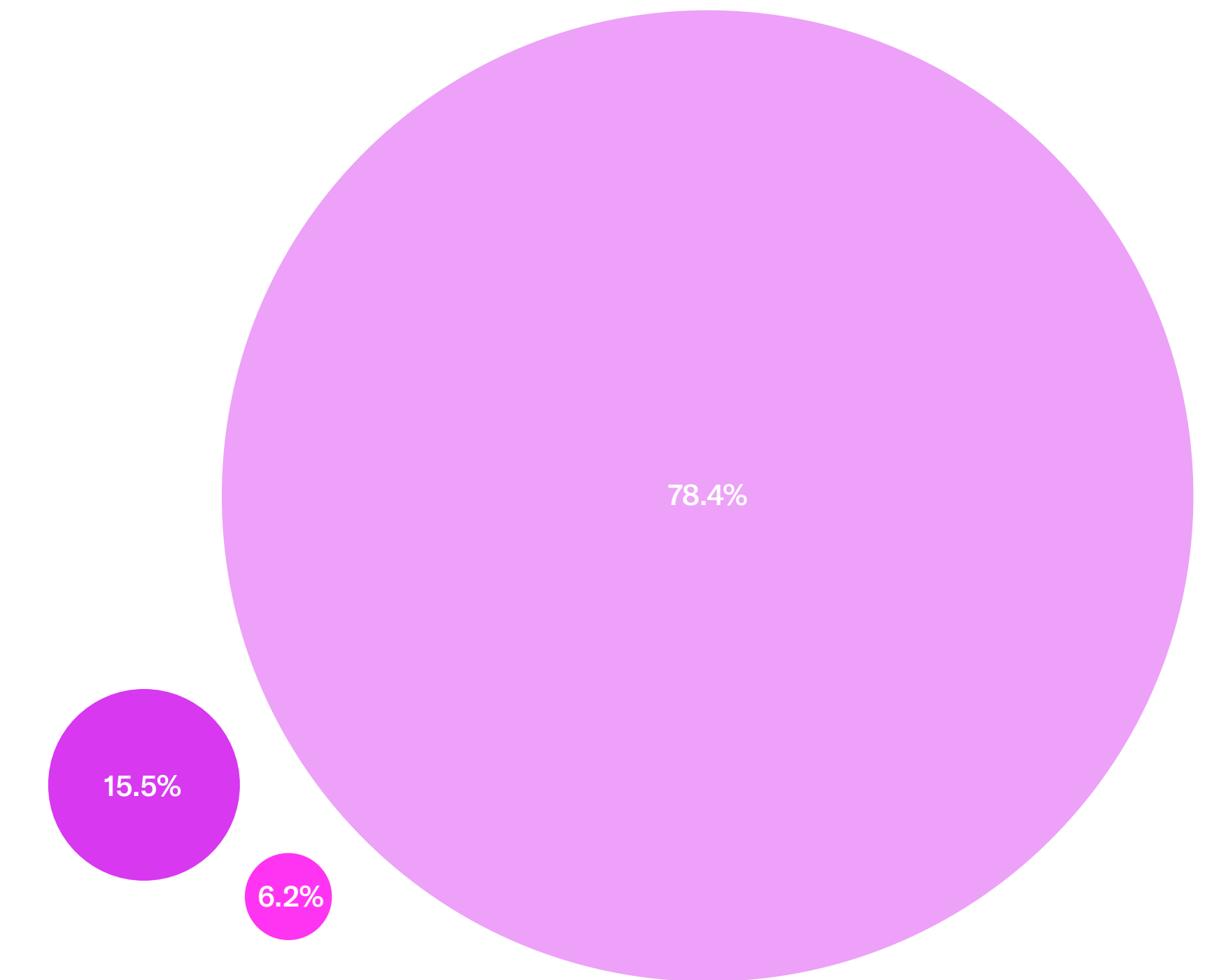
### Biotech ↘

■ Catalonia ■ Rest of Spain ■ International



### Medtech ↘

■ Catalonia ■ Rest of Spain ■ International

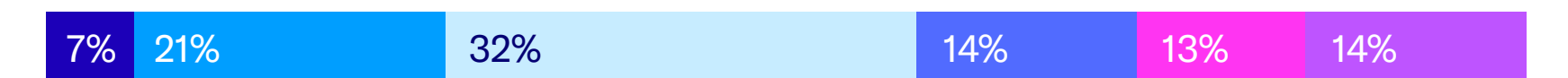


## Breakdown of R&D investment by type of activity (%)

### Biotech ↘



### Medtech ↘



■ Patents ■ Research ■ Development ■ Preclinical ■ Regulatory ■ Clinical

Source: CataloniaBio & HealthTech and EY

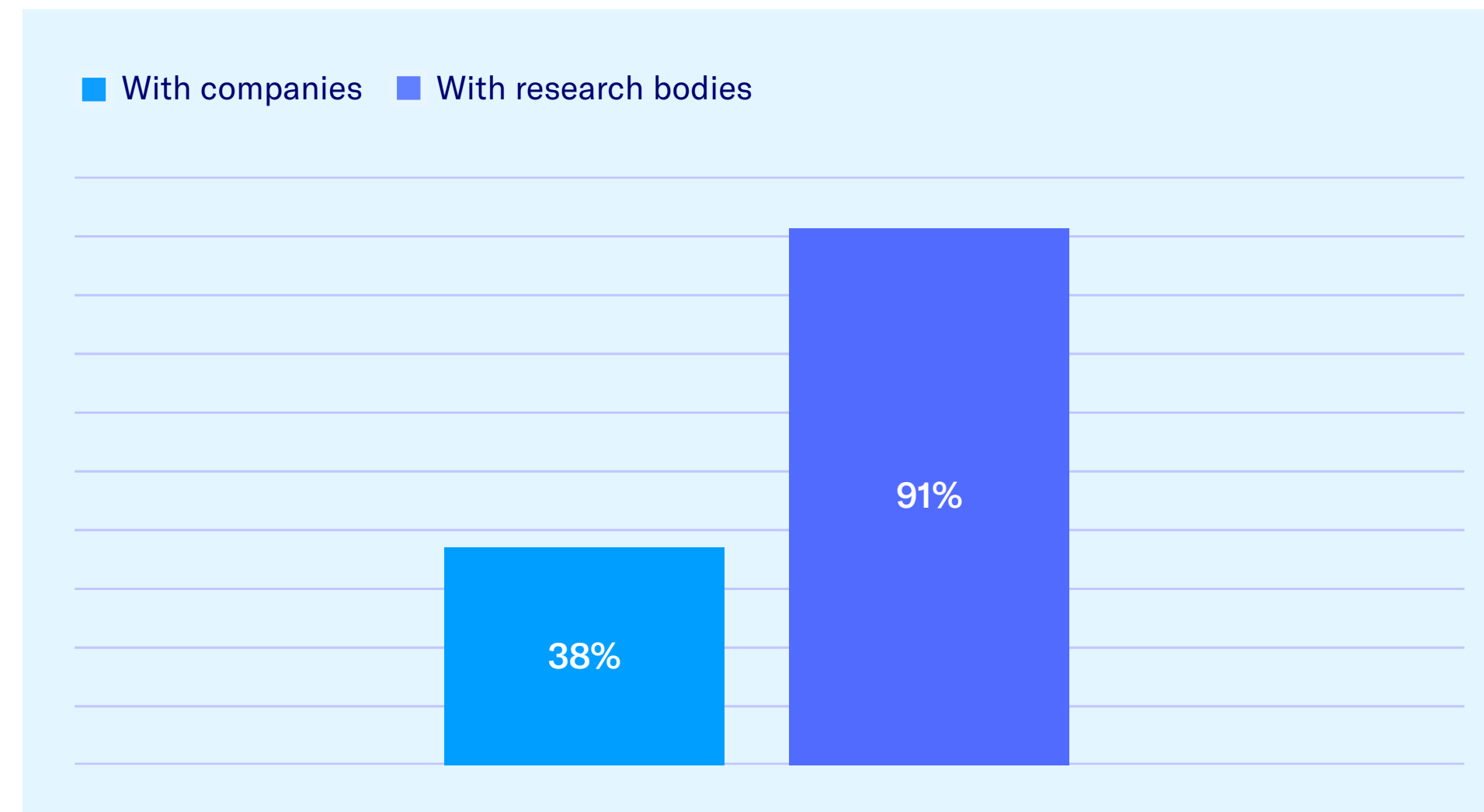
# High level of R&D collaborations among startups and research institutes bodies in the BioRegion

Consistent with the data on R&D investment in the ecosystem, 90% of biotech and medtech startups collaborate with local research bodies. In terms of the private sector, 38% of biotech startups and 48% of medtech companies say they collaborate with other companies. This figure is significant because it shows the knowledge-transfer capacity of the ecosystem.

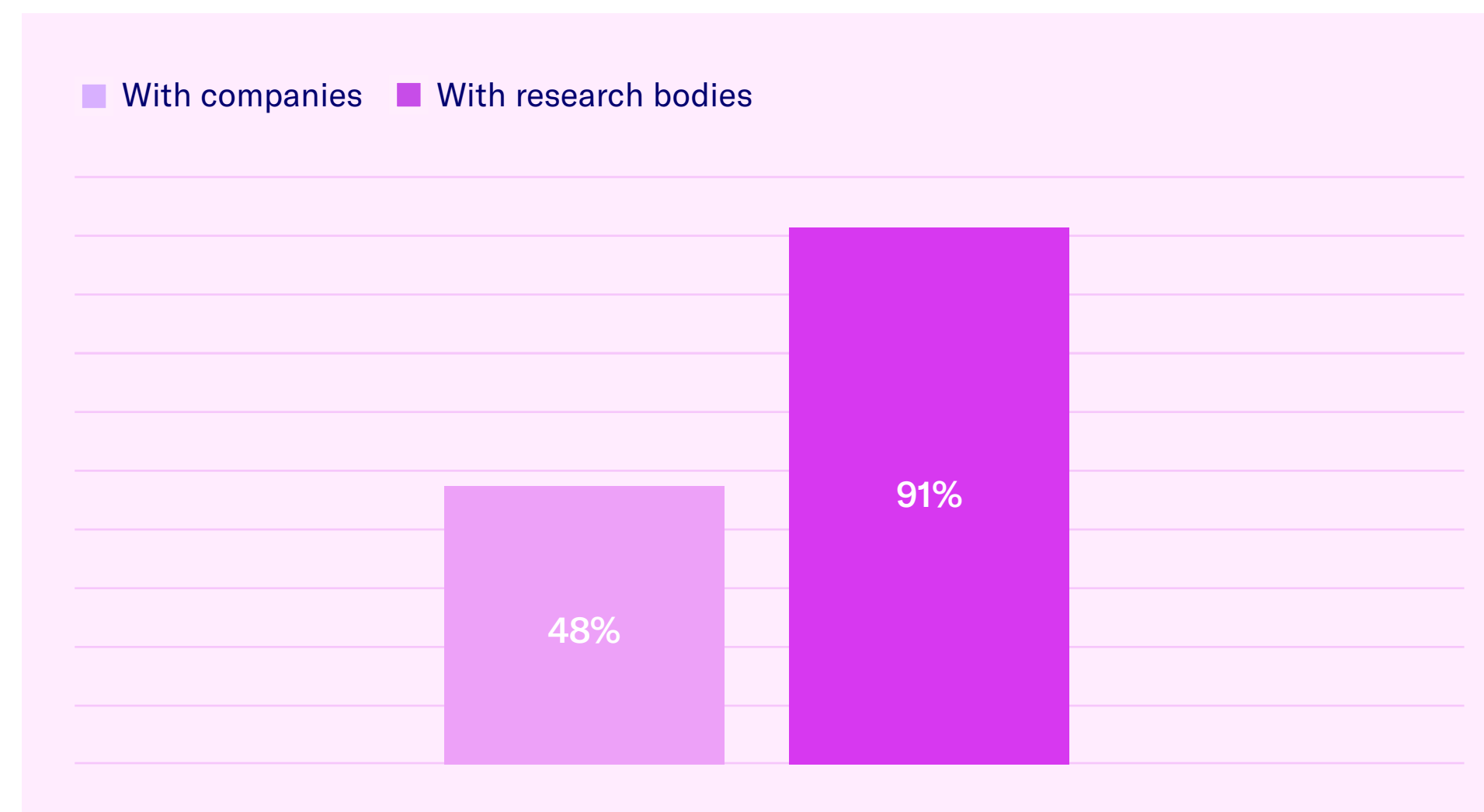
The network of research bodies, hospitals and associated institutes is a key asset for the intensive collaboration activity in innovative ecosystems, where companies compete for the best partners, technology and networks. Noteworthy in this regard are the collaborations of startups in the BioRegion with hospitals and hospital research institutes (50% for biotech companies and 40% for medtech). Data was also collected on collaboration agreements with research centers (13% and 20%) and universities (14% and 18%).

In terms of collaborations with other companies, biotech and medtech startups work with both SMEs (13% and 16%) and large companies (10% and 7%).

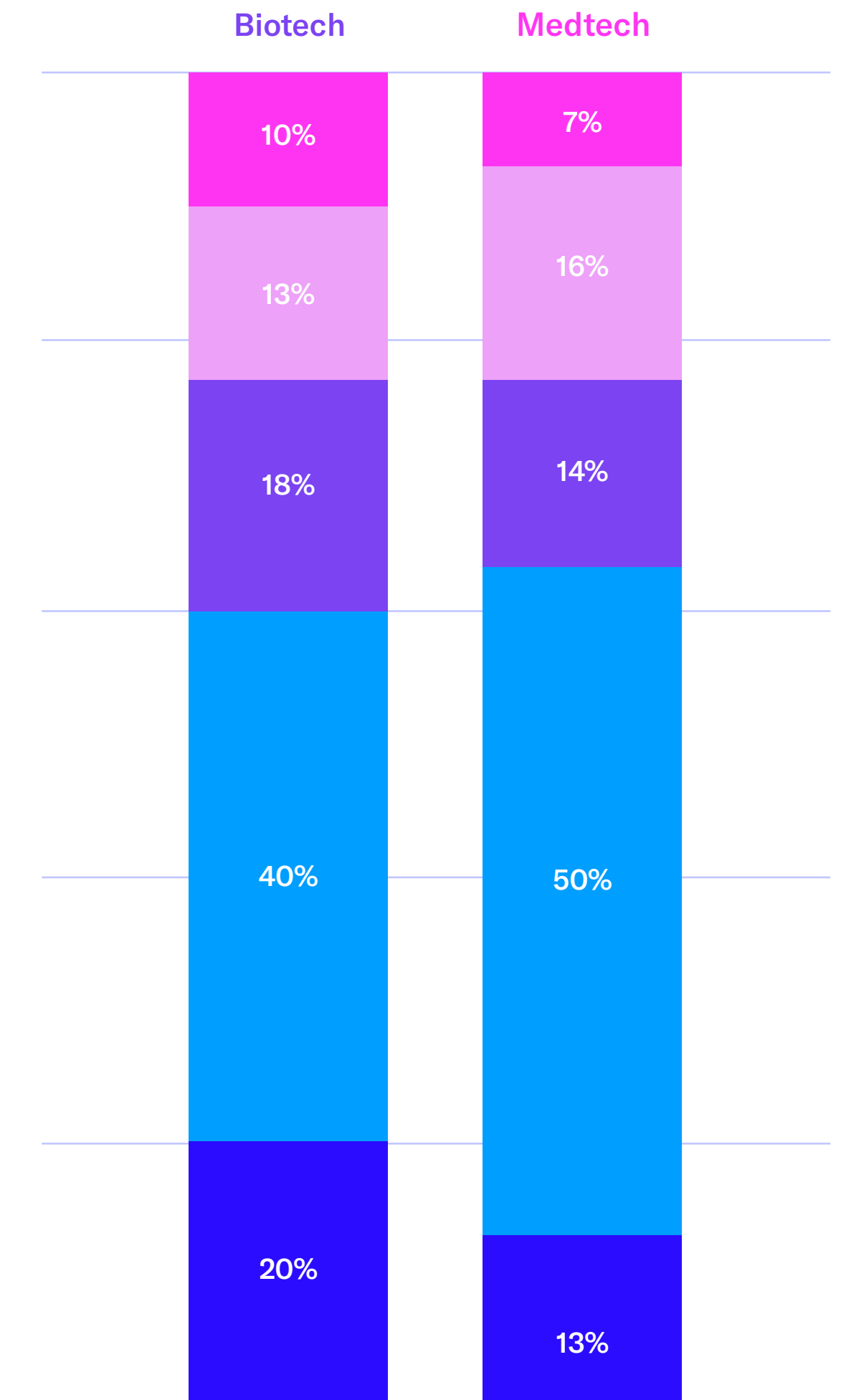
% biotech companies with R&D collaborations



% medtech companies with R&D collaborations



Breakdown of collaboration agreements by type of partner



- Large companies
- Microenterprises and SMEs
- Universities
- Hospitals and Hospital research institutes
- Research centers

Source: CataloniaBio & HealthTech and EY



# More than half of biotech and medtech startups apply for patents to protect their products

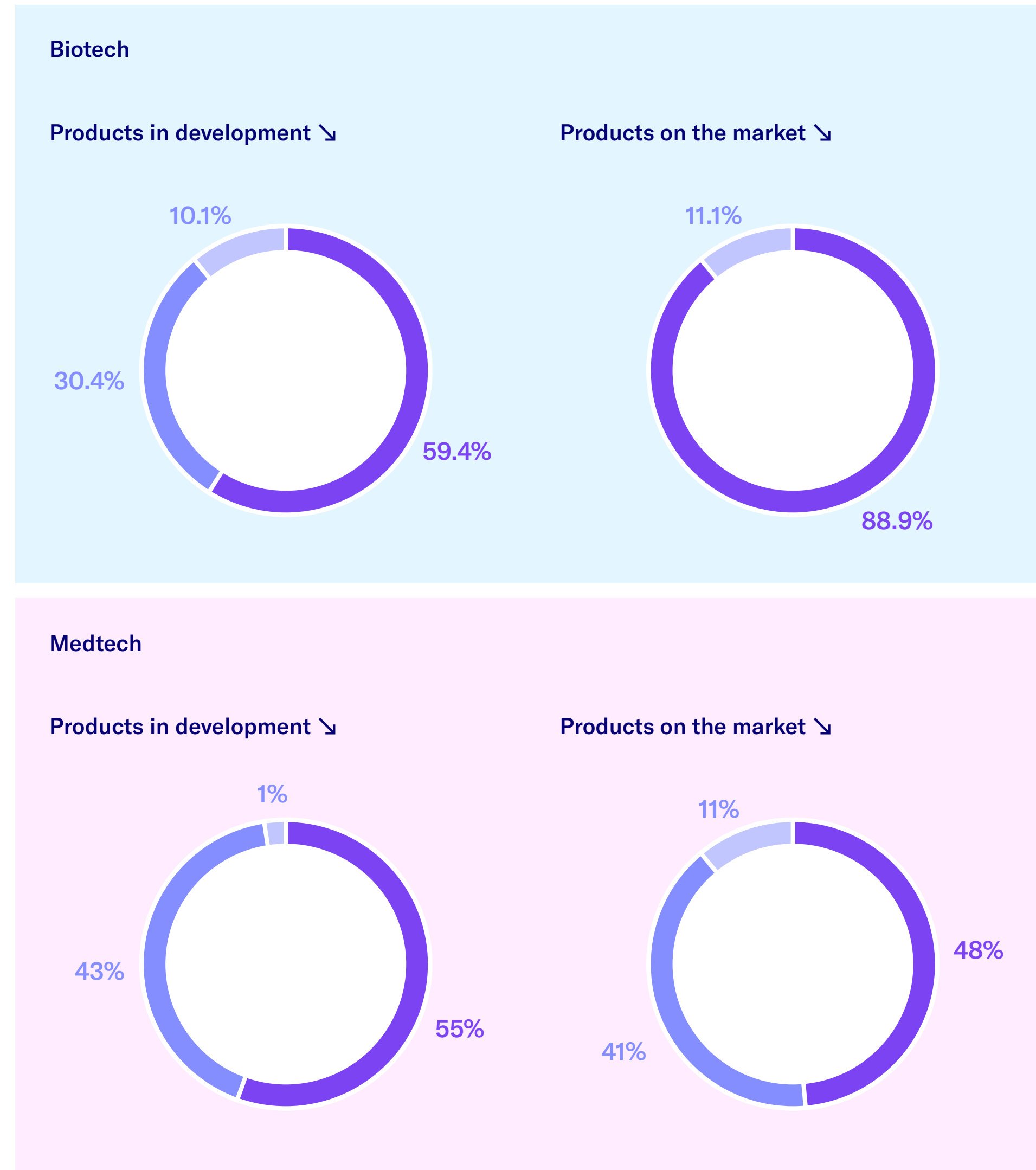
Throughout the development of their products, companies in the BioRegion expand and consolidate their patents to ensure strong, complete protection.

Nearly 60% of patents that protect biotech and medtech products in the development stages are held by the company itself. Of the rest, the vast majority (30% for biotech and 43% for medtech) are patents transferred from an academic institution.

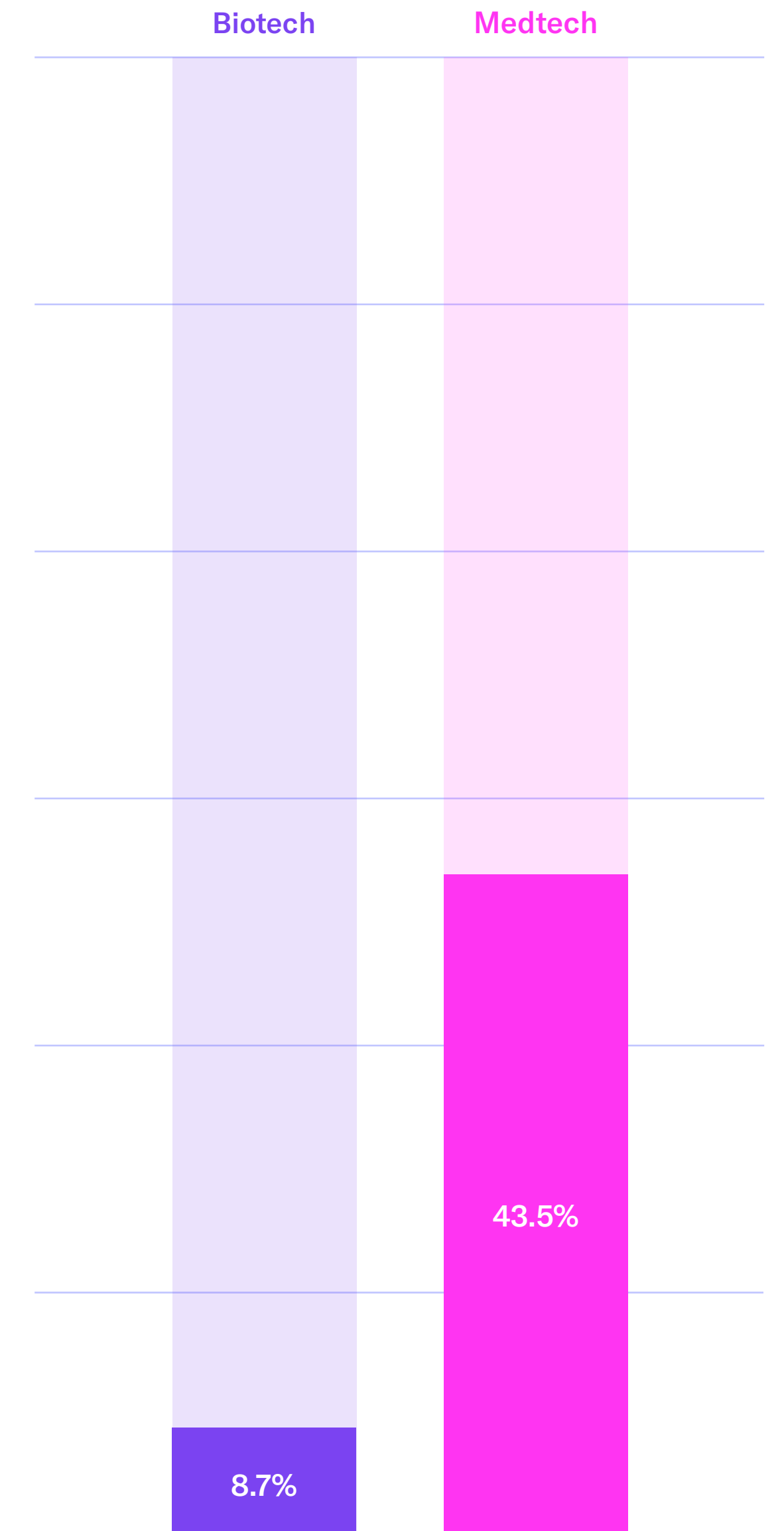
For patents protecting products on the market, nearly 50% of medtech startups say it was the company that applied for the patent. For biotech companies (only 8% of which have products on the market), nearly 90% of the patents held were applied for by the company.

## Origin of patents

- Applied for by the company
- Transferred from an academic institution
- Transferred from another company



## Companies with products on the market



Source: CataloniaBio & HealthTech and EY

04

# Science and technology assets





# The BioRegion's clinical pipeline: moving towards the market and patients

An overview of the 56 therapies being developed in the BioRegion gives us a snapshot of R&D priorities in certain clinical areas and the timeline for some therapies to reach the market and have an impact on patients' health.

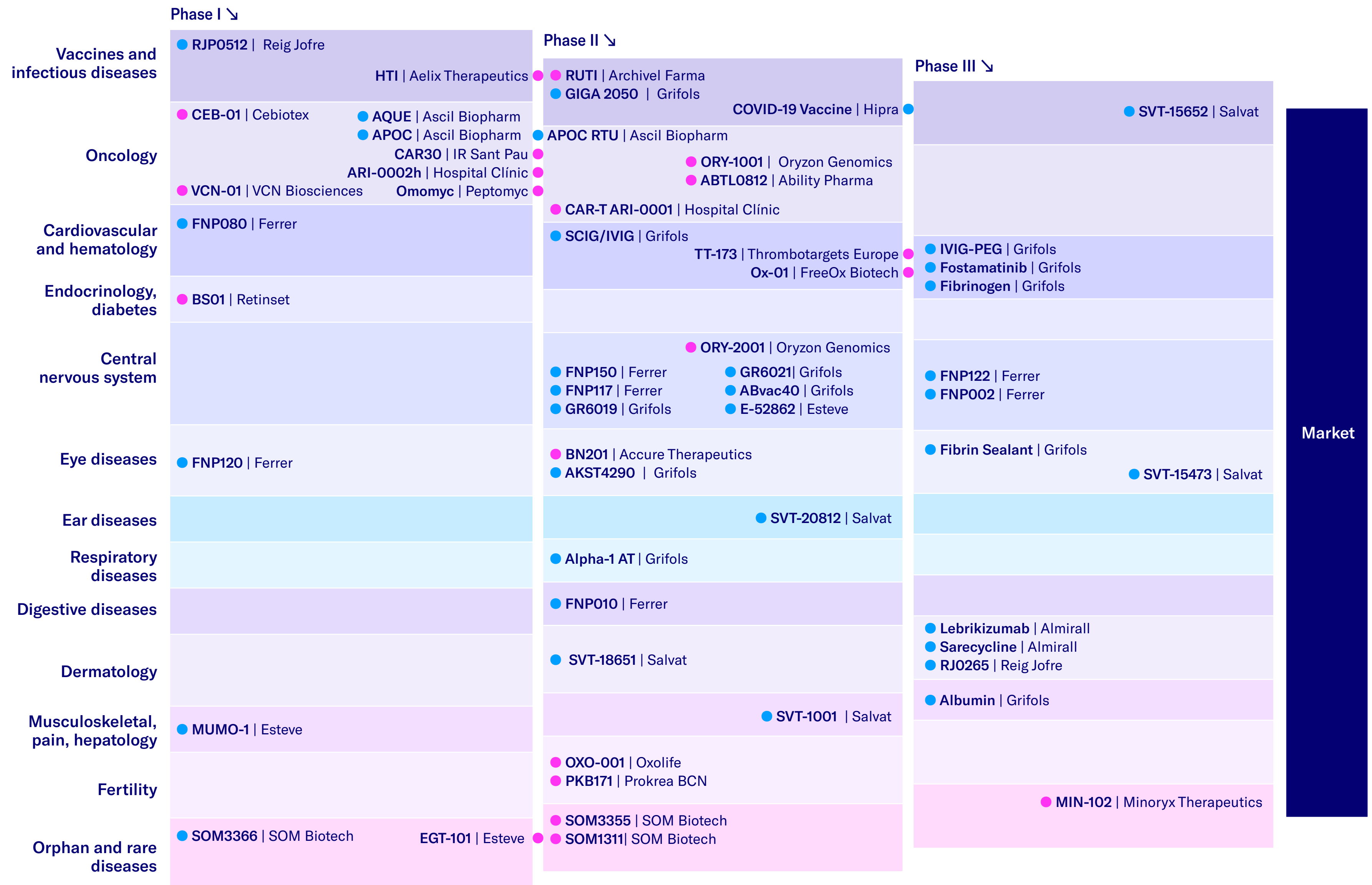
In 2021, biotech companies like Ability Pharma (pancreatic cancer), Oxolife (female fertility) and Peptomyc (tumors) advanced in or announced news on their trials. Companies' efforts are also reflected in solutions to COVID-19: Archivel Farma, Hipra and Grifols are developing several potential treatments for the virus.

The development of non-industrial production CAR-T warrants special mention, as it opens the door to more affordable treatments.

These are advanced therapies that offer good alternatives for specific and personalized treatment in patients that don't respond to conventional options. Hospital Clinic Barcelona already has two, one for patients with acute lymphoblastic leukemia (the only CAR-T developed wholly in Europe to be approved by a regulatory agency) and another for multiple myeloma. Hospital Sant Pau also successfully completed phase I with its CAR-T therapy and will begin another trial in the first quarter of 2022.

Pipeline of pharmaceutical and biotechnology companies

● Pharma ● Biotech



Source: Biocat

Note: Molecules shown between two phases have completed the previous phase or are advancing into the following phase

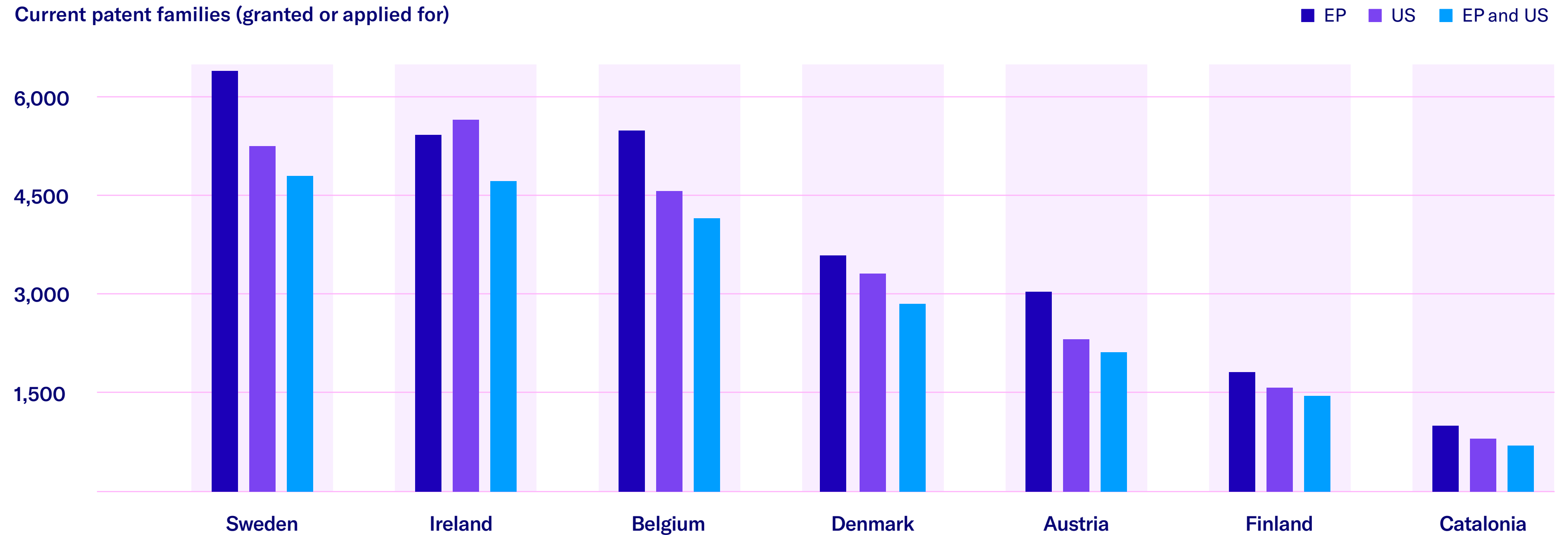
Market

# Adequate progress in protecting the BioRegion's inventions in the EU and US, although the number of patents still needs improvement

Patent indicators are among the most commonly used to judge a region's innovation capacity. For this report, we've used the OECD category "triadic patent families" (a set of patents filed at patent offices in Europe, US and Japan), not including Japan (given its restrictiveness). The analysis includes health inventions (US/EP/WO patent families) applied for in the past 10 years with at least one Catalan applicant and at least one current patent (granted or applied for) in the United States and Europe. The goal is to understand the commercial value and ability to reach significant markets (not the ability to generate patents).

As the graph shows, Catalonia lags behind other countries in number of patents granted and

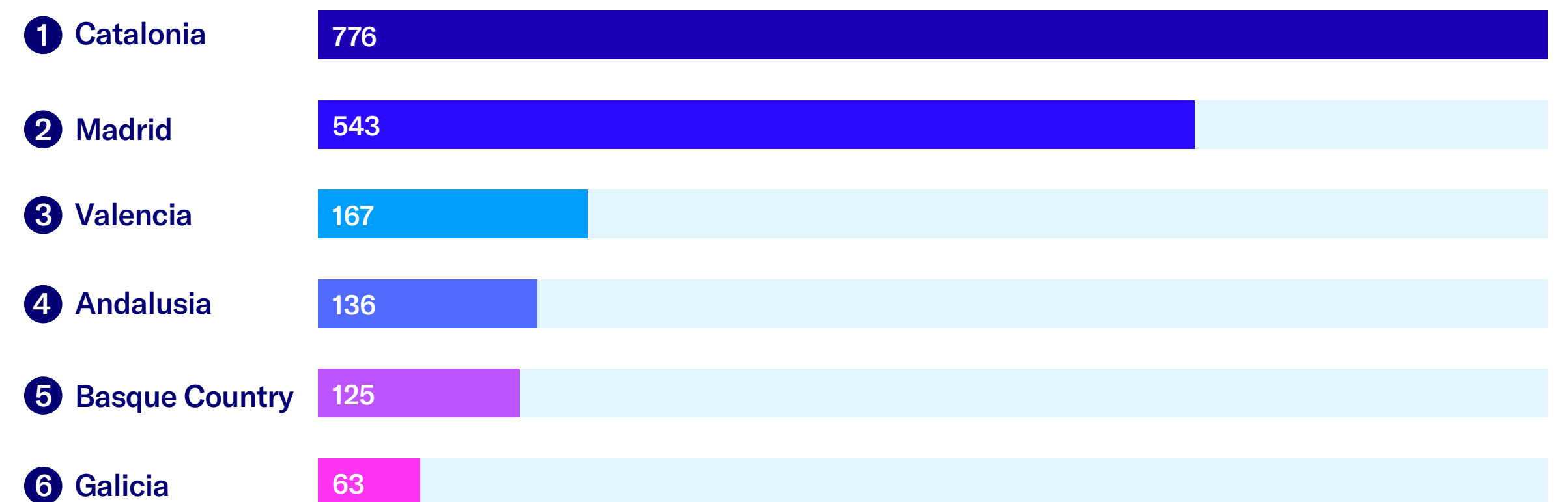
Current patent families (granted or applied for)



currently held in Europe, the US and simultaneously in Europe and the US compared to European countries of a similar size and population. However, the level of protection, in geographic terms, is similar to other countries. Specifically, in Catalonia 71% of all inventions protected in Europe are also protected in the United States, which is comparable to countries like Austria (71%), Sweden (76%) and Belgium (77%).

It is worth noting that Catalonia leads Spain in number of current patent families, making up 35% of the country's total, above the Community of Madrid, which has 25%.

Current patent families (granted or applied for) ↘





# Who has patented the most until 2021?

Analyzing patent families shows the volume of inventions protected by various companies and organizations in the BioRegion. The filters applied in this analysis (triadic patent families applied for over the past 10 years with at least one Catalan applicant that are current in at least the United States and Europe) ensure that the patented inventions have a commercial purpose.

Large companies in the BioRegion have the most inventions protected, by number of patent families.

In general, the percentage of patents granted ranges from 50% to 65% on average for academia, startups and large companies.

Triadic inventions (excluding Japan) currently held by academic institutions that have been transferred to companies through private technology licensing contracts to be exploited commercially are counted under the academic institution if they are still listed as the applicant.

## Top 10 Academia

	Patent families	Patents granted
UPC	18	107
VHIR	15	101
UAB	13	39
CSIC	12	72
IDIBAPS	12	74
CIBER	10	52
UB	10	26
IRB Barcelona	8	83
IGTP	7	10
IRSICAIXA	5	28

## Top 10 Startups and SMEs

	Patent families	Patents granted
Oryzon Genomics	10	109
BCN Peptides	8	131
Minoryx	8	49
STAT-Dx	6	75
Archivel	5	68
Zip Solutions (Era Biotech)	5	40
Quantium Medical	5	7
IUCT	4	31
DR Healthcare	4	30
Inbiomotion	4	26

## Top 10 Large companies

	Patent families	Patents granted
Esteve	58	674
Almirall	22	481
Lipotec	18	193
Ferrer	11	215
Interquim	11	94
Grifols	9	129
HTBA (HealthTech BioActives)	6	71
Bioibèrica	5	26
Salvat	3	43
HIPRA	3	23

05

# Market Access





# Market access begins in the early stages of development

‘Market access’ is the process of making pharmaceutical products and medical technology available to as many people as possible.

This concept has become hugely important over the past 10 years, with the incorporation of increasingly complex and expensive technology, the pressure on healthcare systems to regulate and cover them, and the implementation of new assessment and control mechanisms.

As most health systems in Europe are public, maximizing market access and getting reimbursed for these products requires a complex product assessment process and negotiations with authorities (which may be national or regional) and hospitals. The table shows the main markets for the European sector (which make up over 50%).

This isn’t the case in the United States, where the private system is the most important in terms of value and coverage. It is a free market where assessment mechanisms are less stringent, and which is governed mainly by competition.

Notes: Data from 2018 (France and Italy); Data from 2019 (Germany, Spain and United States); Data from 2020 (United Kingdom).

## Characteristics of healthcare systems

	Germany	United Kingdom	France	Italy	Spain	United States
Healthcare expenditure	€403B 85% Public, 15% Private	€320B 82% Public, 18% Private	€265B 73% Public, 27% Private	€152B 73% Public, 27% Private	€101B 71% Public, 29% Private	€3,800B 58% Public, 42% Private
Expenditure as % of GDP	€3,438B 10% Public, 1.8% Private	€3,438B 10.9% Public, 2.4% Private	€2,467B 7.8% Public, 2.9% Private	€1,849B 6% Public, 2.2% Private	€1,232B 5.8% Public, 2.4% Private	€18,952B 11.6% Public, 8.4% Private
Type of public system	Decentralized with insurers	Decentralized by region	Centralized	Decentralized by region	Decentralized by region	By insurers and out-of-pocket (not insured)
Type of private coverage	Duplicate and supplementary	Complementary	Complementary	Supplementary	Supplementary	Complementary and supplementary
% population covered (public and private)	89% Public, 11% Private	100% Public, 15% Private	100% Public, 96% Private	100% Public, 11% Private	100% Public, 17.5% Private	24% Public, 54% Private, 14.5% Mixed, 8.5% Out-of-pocket
Regulatory agency	EMA BfArM	MHRA	EMA HAS	EMA AIFA	EMA AEMPS	FDA
Main payers	GKV	NHS	UNCAM	Regional Governments and ASLs	Regional Governments	CMS and private insurer

Sources: World Data Bank; International World Data Bank; International Health Care System Profiles; Commonwealth Fund; Centers for Medicare and Medicaid Services; Health Systems in Transition; OECD; Alira Health expertise and primary research with payers.

EMA: European Medicines Agency; FDA: US Food and Drug Administration; AEMPS: Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency of Medicines and Medical Devices); AIFA: Agenzia Italiana del Farmaco (Italian Medicines Agency); HAS: Haute Autorité de la Santé (French National Authority for Health); BfArM: Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices); MHRA: Medicines and Healthcare products Regulatory Agency; ASL: Azienda Sanitaria Locale (Local Health Authorities); CCAA: Comunitats Autònomes (Spanish regions); UNCAM: Institut für das Entgeltsystem im Krankenhaus (French National Union of Health Insurance Funds); GKV-SV: Gesetzlichen Krankenversicherung (National Association of Statutory Health Insurance Funds); NHS: National Health Service; CMS: Centers for Medicare and Medicaid Services.

# Europe is an example of rigorousness and standardization of assessment processes for drug access

Drugs, after gaining regulatory approval, must follow specific assessment processes on a national level, which may be in addition to the regional level in countries like Italy and Spain, to effectively gain access to the market.

These processes can be broken into two categories:

- Health Technology Assessment (HTA): systematic assessment of the properties and effects of technology, comparing the added benefit over existing alternatives
- Pricing & Reimbursement (P&R) Negotiations: negotiations regarding public reimbursement and the price to be paid

Different mechanisms are used to assess the products and set prices, which vary according to the market and type of product: original, generic/hybrid, innovative and orphan.

It must be noted that patient experience is increasingly considered as an assessment mechanism, although there is still a long way to go before it is truly significant.

## Market access - Drugs

✔ Efficacy
🛡️ Safety
👤 Patient
∅ No

	Germany	United Kingdom	France	Italy	Spain	United States
Main authorities	<b>HTA:</b> G-BA and IQWiG <b>P&amp;R:</b> GKV	<b>HTA and P&amp;R:</b> NICE	<b>HTA:</b> HAS-CT <b>P&amp;R:</b> CEPS	<b>HTA:</b> AIFA CTS <b>P&amp;R:</b> AIFA CPR	<b>HTA:</b> AEMPS <b>P&amp;R:</b> DGCBSyF, CISNS, CIPM	<b>HTA:</b> ICER <b>P&amp;R:</b> PBMs
Level of evidence required	●●●	●●○	●●○	●○○	●○○	●○○
Type of evidence assessed	✔🛡️👤	✔🛡️👤	✔🛡️	✔🛡️	✔🛡️	✔🛡️
Financial studies	Informal Budget impact analysis	Cost-effectiveness	Budget impact analysis	Budget impact analysis	Budget impact analysis	∅
Patient participation	Presence Impact	Presence Impact	Presence Impact	Presence Impact	Presence Impact	Presence Impact
Internal reference pricing	ATC-3	∅	ATC-5	ATC-5	ATC-5	∅
External reference pricing	∅	∅	Depends on HTA results	Informal	Informal	∅
Special considerations for orphan drugs	<b>HTA:</b> Yes <b>P&amp;R:</b>	<b>HTA:</b> Yes Scotland <b>P&amp;R:</b> ∅	∅	<b>HTA:</b> ∅ <b>P&amp;R:</b> Yes	<b>HTA:</b> ∅ <b>P&amp;R:</b> Yes	∅

Sources: : WHO - Medicines Reimbursement Policies in Europe; The Commonwealth Fund; European Observatory on Health Systems Research and Management; Orphanet; Global Alliance for Patient Access; Alira Health expertise and primary research with payers.

ATC: anatomical therapeutical code; IQWiG: Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care); G-BA: Gemeinsamer Bundesausschuss (Federal Joint Committee); GKV-SV: Gesetzlichen Krankenversicherung (National Association of Statutory Health Insurance Funds); NICE: National Institute for Health and Care Excellence; HAS-CT: Commission de la Transparence (Transparency Committee); CEPS: Comité économique des produits de santé (Economic Committee for Health Products); CTS: Commissione Tecnico Scientifica (Technical Scientific Committee); CPR: Comitato Prezzi e Rimborso (P&R Committee); DGCBSyF: Dirección General de Cartera Básica de Servicios del Sistema Nacional de Salud y Farmacia (Directorate-General of the Basic Portfolio of National Health System and Pharmacy Services); CIPM: Comisión Interministerial de Precios de los Medicamentos (Interministerial Drug Pricing Commission); CISNS: Consejo Interterritorial del Sistema Nacional de Salud (Inter-territorial Council of the National Health System); ICER: Institute for Clinical and Economic Review; PBM: Pharmacy Benefit Manager.



# Europe sets the pace and direction of access to digital health and medical technology

There are no established processes for effective market access for *in vitro* medical devices and diagnostics<sup>1</sup> after obtaining CE and UKCA marking in Europe and the United Kingdom, respectively, or FDA approval in the United States.

Despite also following HTA and P&R, implementation varies widely based on:

- Assessment on national, regional and local levels (with less transparent assessment criteria than for drugs) according to the type of technology
- Use of existing or new pricing codes or negotiating independent purchases, with implications for the source of funding

For digital technology, the level of regulatory development is still very low worldwide. Germany is the only country in the EU with a specific process (DiGA, for Digital Health Applications), although a similar model is being debated in France. The United Kingdom is the most advanced country, with processes like the NICE Evidence Standards Framework for DHTs and Artificial Intelligence in Health and Care Award.

<sup>1</sup> Regulated at the European level by MDR and IVDR.

## Market access - Medical technology

■ National 
 ■ Regional 
 ■ Hospital 
 ■ Insurer 
 ✓ Efficacy 
 🛡️ Safety 
 👤 Patient 
 ∅ No

		Germany	United Kingdom	France	Italy	Spain	United States
Main authorities		G-BA, GKV and InEK	NICE and CCGs	HAS-CNEDiMTS, CEPS and ATIH	MoH-DGFDM	MoH and Regional Health Authorities	FDA, AHQR, HFCA
HTA level							
Evidence required							
Financial studies		∅	Cost-effectiveness	Informal Budget impact analysis	Budget impact analysis	Informal Budget impact analysis	∅
Coverage by codes	Inpatient	DRG, NUB, or ZE	HRG	CCAM and wDRG	NTPO	Basic portfolio	CPT
	Outpatient	EBM	HRG	LPPR and CCAM	NTPA	Basic portfolio	HCPCS
Specific processes for digital health		DiGA	ESF	∅ Expected in 2022 Social Security Law	∅	∅	∅

Sources: ISPOR; Websites of national authorities; Centers of Medicare & Medicaid; Alira Health expertise and primary research with payers.

G-BA: Gemeinsamer Bundesausschuss (Federal Joint Committee); GKV-SV: Gesetzlichen Krankenversicherung (National Association of Statutory Health Insurance Funds); InEK: Institut für das Entgeltsystem im Krankenhaus (Institute for the Hospital Remuneration System); NICE: National Institute for Health and Care Excellence; CCG: Clinical Commissioning Group; ATIH: Agence Technique de l'Information sur l'Hospitalisation (Technical agency for information on hospitalization); CNEDiMTS: Commission Nationale d'Evaluation des Dispositifs Médicaux et des Technologies de Santé (National Commission for the Evaluation of Medical Devices and Health Tech); CEPS: Comité économique des produits de santé (Economic Committee for Health Products); MoH: Ministry of Health; DGFDM: Direktorat Generale Farmaci e Dispositivi Medici (General Directorate of Medicines and Medical Devices); AHRQ: Agency for Healthcare Research and Quality; HFCA: Health Care Finance Administration; ESF: Evidence Standards Framework.

# Pharmaceutical products

## Trends in market access

### General ↘

- Use of RWE (Real World Evidence) as a requirement for access and to adapt contracts according to results
- Exponential growth in use of Big Data and Analytics
- Digitalization and transformation of company type

### Europe ↘

- Increased focus on economic studies (cost-effectiveness and budget impact analysis) in assessments
- Increased importance of patient quality of life and experience in assessments
- Implementing innovative contracts, with special focus on payment by results and RWE

### United States ↘

- Increased cost pressures and pricing negotiations, even though not regulated
- Expanding development and use of precision medicine

### Catalonia / Spain ↘

- Change in assessment of new drugs towards cost-effectiveness model
- New drug funding methods (shared risk and payment by results) and increase in use of REvalMed (Red de Evaluación de Medicamentos del Sistema Nacional de Salud - Drug Evaluation Network of the SNS)
- Incorporating patients into hospital procurement process

## Challenges in market access

### General ↘

- Adapt to growing competition from generic and biosimilar pharmaceutical products
- Adapt business model to be able to provide precision medicine
- Anticipate supply-chain interruptions
- Protect against data breaches and other cybersecurity threats

### Europe ↘

- Adapt to HTA and P&R reforms coming in the near future
- Find new funding methods beyond the product, value-added services
- Include patients in decision-making regarding new drugs

### United States ↘

- Make production on demand more flexible
- Predict decrease in demand for prescription drugs
- Meet growing consumer expectations and manage difficulties maintaining brand health

### Catalonia / Spain ↘

- Create special coverage or budgets for expensive drugs, focusing especially on genetic medicine



# Medical technologies and digital health

## Trends in market access

### General ↘

- Adopting Artificial Intelligence (AI) and Big Data for therapeutic decision-making
- Increase in digital therapies on the market
- Universal adoption of telemedicine
- Increased use of precision medicine, precision surgery and robotics
- Proliferation of the Internet of Medical Things (IoMT)

### Europe ↘

- Implementing specific assessment processes for technological innovation, especially for digital health and AI
- Incorporating financial analysis into decision-making

### United States ↘

- Greater weight of social determinants of health like quality of life for patients and carers
- Increased cost pressures and pricing negotiations, even though not regulated

### Catalonia / Spain ↘

- Increase in genetic diagnostics in the public health system
- Incorporating patients into hospital procurement process

## Challenges in market access

### General ↘

- Integrate role of healthcare professionals and AI
- Adjust health-at-home care model using new technology available
- Prevent data breaches and cybersecurity threats
- Anticipate evolution of early diagnosis and its impact on the market

### Europe ↘

- Adapt to growing scrutiny and assessment of clinical and financial evidence, especially under new European regulations (MDR and IVDR, for medical devices and for *in vitro* diagnostics, respectively)
- Incorporate wearables and software into the funding process
- Integrate devices to measure patients' health conditions into digital clinical history systems

### United States ↘

- Adapt to a new regulatory environment that is increasingly restrictive and harmonized

### Catalonia / Spain ↘

- Adapt regulations and processes to European regulations (MDR and IVDR, for medical devices and for *in vitro* diagnostics, respectively)
- Standardize assessment and procurement processes for medical technology and digital health
- Create/adapt budgets and codes based on the real situation of the medical technology and digital health market

# Methodology

The BioRegion of Catalonia is the life sciences and healthcare ecosystem in Catalonia and the subject of this Report, which Biocat has published since 2009. Since 2020, the Report has been compiled with collaboration from CataloniaBio & HealthTech, and from ACCIÓ for this 2021 edition. Amgen, a global leader in pharmaceuticals, has accompanied the development of the Report since the very first edition.

The sources used are referenced in each case, but this section on Methodology specifically defines the concepts or guidelines used in order to help readers better understand some figures or indicators. If you have any questions about this, or if you feel your company hasn't been properly reflected in the chapter on investment, please contact us at [comunicacio@biocat.cat](mailto:comunicacio@biocat.cat).

The analyses in this Report are based on information from the [Biocat Directory](#), which covers more than 1,500 companies and organizations operating in Catalonia in the life sciences and healthcare arena. This platform is managed in collaboration with Venture Valuation, the owners of BiotechGate, one of the most complete international databases in this sector. It is available at [catalanlifesciences.com](http://catalanlifesciences.com). This data is then cross-referenced with the Biocat CRM, which has nearly 10,000 active organizations and over 30,000 contacts.

The main subsectors of companies are biotechnology, pharmaceuticals, medical technology and digital health. The definitions of the subsectors used in this report are available in the Biocat Directory.

For the data on the companies' turnover and employment, the source used was the SABI database (Iberian Balance Sheet Analysis System), which gets its information from the annual accounts submitted to the Business Registry (latest data available 2020). Companies that operate in the area but don't have their official business address in Catalonia are not counted.

The method for calculating the sector's weight in terms of the GDP (gross domestic product) is available on page 45 of the 2017 Biocat Report, which is on the Biocat website.

The definition of a startup used in this Report requires a special note. On one hand, it is used in its most common sense, to denote companies established within the past 10 years. On the other, it is used in a broader sense, taking into account aspects associated with the activity and characteristics of the companies, whether they are innovative or technologically disruptive, based on entrepreneurship and focused on research, services or products that address complex issues. This group is where we find most of the companies we refer to as deeptech or deepscience firms, working in areas like artificial intelligence (AI), robotics, computer vision, virtual or augmented reality (AR/VR), genomics, immunotherapy, synthetic biology, bioinformatics, 3D and bio printing, etc., which are also classified as startups in the Report.

To study investment in startups, Biocat follows emerging and innovative companies in the main subsectors established in the BioRegion directly. Data on public and private capital, through formal investment vehicles or instruments, is compiled. The data usually comes from the company itself or public sources (press releases or news articles, investors, VC reports, etc.).

To analyze the stock market, in collaboration with international consultancy EY, EU countries have been selected for comparison that are similar in GDP, population or size (Finland, Denmark, Sweden, Austria, Ireland and Belgium).

The indicators on company activity in the 'Other insights\* on business activity' chapter are taken from a survey of CataloniaBio & HealthTech members conducted in September 2021. A total of 87 companies participated from all subsectors, but this Report only looked at

the results of biotech and medtech companies with turnover under €10M. The results were compiled and analyzed in collaboration with international consultancy EY. The data on the activity of specialized investors -VC and crowdequity platforms- is also from a survey of most of these investors conducted by CataloniaBio & HealthTech to compile quantitative data on the operations carried out. In November 2021, a session was held to provide additional context, at which we discussed and assessed the results of the survey.

To monitor the clinical pipeline of biotechnology and pharmaceutical companies, the website [clinicaltrials.gov](http://clinicaltrials.gov) was used, along with information provided by the companies themselves.

The analysis of innovations in the sector is, like in the previous report, a collaboration with industrial and intellectual property consultancy Pons IP. So, while last year we studied the patents granted, this year we wanted to look at the reality of technology transfer. We analyzed the past 10 years of triadic patent families (EP, US and WO) with at least one Catalan applicant and with at least one current patent in the United States and Europe, granted or applied for, that are current on payment of fees, or have an application being processed. These two conditions mean that the patent documents identified are for developments in the sector with a high level of quality, which increases their potential for commercialization. The same methodology was used for the rest of the countries in the comparison.



2021 BioRegion of Catalonia Report

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