

# The Swedish Drug Discovery and Development Pipeline 2023



## 506 Projects

506 RnD projects, from discovery to Phase III. Most projects are within oncology and neurology.



## 159 Companies

159 Swedish RnD pharma and biotech companies are actively developing new drugs. 63% of the companies have projects in clinical phase I-III.



## Highlights

International outlook, comparisons over time and focus on advanced therapies.

**swedenBIO**  
The Swedish Life Science Industry Organization

**VINNOVA**  
Sweden's Innovation Agency

**CITELINE**  
a norstella company





This report has been produced by SwedenBIO  
in cooperation with Citeline and Business Sweden,  
with support from Vinnova.

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Most importantly, thank you to all the companies who answered the survey and provided the detailed pipeline information required to create this comprehensive

overview of the Swedish pharmaceutical ecosystem and pipeline.

ORIGINAL DATA

The original data presented in this report was collected during the period October to December 2022. Please see the Methods section at the end of the report for details.

DISCLAIMER

The content of this report is based on information gathered in good faith and is believed to be correct at the time of publication.

PARTNERS

**Citeline** (a Norstella Company) powers a full suite of complementary business intelligence offerings to meet the evolving needs of health science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze data used to drive clinical, commercial, and regulatory-related decisions and create real-world opportunities for growth. Their global teams of analysts, journalists and consultants

keep their fingers on the pulse of the pharmaceutical, biomedical and medtech industries.

**Business Sweden** is a semi-governmental organization with the mission to support Swedish companies to grow their business internationally and to help foreign companies invest and grow in Sweden. Business Sweden has a footprint in all major industry sectors in Sweden and life science is a key focus area, delivering on the country's ambitions in innovation and sustainability.

SUPPORT

The production of this report and the construction of an underlying database has been supported by Vinnova, the Swedish innovation agency.

MAIN PUBLISHER

SwedenBIO is the Swedish life science industry organization representing over 300 companies within pharma, biotech and medtech. SwedenBIO has mapped the Swedish drug development pipeline since 2006.

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## NATIONAL FOREWORD

# A leading life sciences nation

Sweden is and should remain a leading life sciences nation. The life sciences industry is one of Sweden's economic base industries with a significant share of our exports. A strong national life sciences-sector contributes in a major way to improving the health and quality of life of the population, as well as building economic prosperity and strengthening Sweden's position as a leading knowledge-based nation.

Sweden now holds the EU Presidency. Life sciences is one of the Presidency's focus areas with emphasis on cancer, antimicrobial resistance, and the implementation of precision health. The latter comes with tremendous possibilities for society but also presents challenges that we need to address. Implementing precision health will among other things demand a cultural shift to enable the use of large data sets and AI for early disease detection and diagnosis, and modified regulatory processes for the development and use of new advanced therapies. It is important for patients in Sweden and the EU that this transition is as swift and smooth as possible. This transition is also crucial for the Swedish industry developers of advanced therapies to stay competitive and to be able to develop their products here in Sweden.

The life sciences sector rose to the challenge for the Covid-19 pandemic. Research has never been more important, and it is essential that we continue to invest in research and innovation. The sector needs to continue intensify its efforts to prevent and at the same time be better prepared for the next pandemic as well as to move towards fossil free business operations.

The work of the Government in this area is based on the national life sciences strategy. Many goals have been achieved in collaboration with the life sciences sector since the launch of the strategy in late 2019. The key for continued development is to further build on the strong partnership and close cooperation between the public sector, healthcare, business sector and universities.

The ability of Swedish companies to develop, utilize and export novel technology and services is fundamental for the development of our business sector as well as our society. That ability needs to be strengthened – smartly, selectively and in collaboration – so that companies continue to develop and grow in Sweden. The Government will be an active partner in this process.

**Ebba Busch**  
Minister for Energy, Business and Industry



Foto: Nina Andersson/Regeringskansliet

## ABOUT THE REPORT

# Welcome to the 2023 Swedish pipeline report

In your hand, you hold a comprehensive, up-to-date overview of the Swedish pharmaceutical pipeline and the ecosystem of Swedish companies that create it. We present 159 companies with headquarters in Sweden, currently active in 506 drug discovery and development projects.

## International outlooks

We start the report with a perspective from an international point of view. How does Sweden place in international competition? In this overview, numbers from the database Pharmaprojects has been used to enable international comparisons. The rest of the report goes deeper into details, based on information collected from the companies themselves. We return to international comparisons throughout the report, for example on pages 13, 27 and 31.

## Company landscape

The first section of the report maps the landscape of drug developing businesses in Sweden. How big are the companies, where are they located, and how are they funded? How many employees do they engage, and in which degree are they internationally connected? Read about this in pages 8-25. All 159 companies are listed in the appendix. For a digital version that allows for sorting and filtering, please visit SwedenBIO.se to download the company list.

## Pharma pipeline

The second section presents an overview of the Swedish pharmaceutical pipeline. How many projects are in which phases? Which therapeutic areas are most frequent? And which modalities are on the rise? Read more about this in pages 26-35. All 506 projects are listed in the appendix and available to download in a digital format from SwedenBIO.se.

## Selected highlights

In the third section, we present some highlights from the report. We then focus on incentives for certain development areas, such as orphans and reformulations. We finalize the report with a focus on the promising ATMPs and the future of precision medicine. Not to forget, the essential methods section, for all of you who care about data collections and definitions.

## Perspectives

This report is produced by SwedenBIO, the industry organization for life science companies –but we haven't done it alone. We had the privilege to create this report with the support of dedicated partners. For the first time, we have the international intelligence agency Citeline as a partner, providing the international outlook on page 6. Like with previous editions Business Sweden is a proud partner of the report. You can read their perspectives and an invitation to the international community to join Sweden on page 16. The report is also supported by Vinnova, the Swedish innovation agency, and they share their take on the importance of innovation for a sustainable future on page 19. At last but not least, SwedenBIO provides a reflection on the necessity to support the entire value chain on page 37.

We wish you a joyful and inspiring reading!

**Maja Neiman**  
Editor, SwedenBIO



INTERNATIONAL PERSPECTIVE: CITELINE

# Sweden punches above its weight in European innovation

The Swedish pharmaceutical pipeline stands strong amongst European peers, but only attracts a fraction of the funding in the region, an analysis of Pharmaprojects data shows.

Introduction

Sweden has a long heritage as a global exporter of scientific and therapeutic innovation. Its foundations are built upon its world-class research-based universities, the legacy of companies like Astra Zeneca, and a large manufacturing presence.

Domestic biopharma companies are active in an innovation pipeline of 351 therapeutics, giving the country an outsized footprint within the wider European region. Sweden’s nearest rivals all host the global headquarters of big pharma multinationals, so its prominence is led by local success stories. One of the most important clinical breakthroughs of 2022 – lecanemab for Alzheimer’s disease – was discovered by Stockholm-based BioArctic.

However, the lack of broader investment in Swedish life sciences is a challenge that needs to be addressed. The level of financing is increasing slowly, with a record \$800m raised in 2021, although this does not match the scale of ambition within Sweden’s pipeline. For Sweden to be able to sustain its vibrant biotech ecosystem, new ways of attracting investors must be explored.

A large and diverse domestic pipeline

The Swedish pharma R&D pipeline currently stands at 351 drugs under active development, according to the industry database Pharmaprojects. As shown in Figure 1, Sweden ranks fifth individually on this measure within Europe. When tallied with its neighbours in the Nordics, the overall region sits behind only the UK and Switzerland. This is a hugely impressive contribution, certainly relative to the economic size of the traditional EU5.

Sweden also has one of the highest proportions of preclinical-stage drug candidates amongst its peers. Such candidates are less likely to develop into approved drugs for patients owing to risks in R&D. However, a burgeoning presence in early-stage biotech research is a positive indicator for the innovation ecosystem within Sweden. Domestic companies are filling their pipelines with internally discovered assets. In turn, these will become the therapeutic breakthroughs of the future as the cutting-edge science progresses. This contrasts the mature pharma-led countries such as Switzerland and Denmark, which are more reliant upon external innovation and in-licensing.

“Domestic companies are filling their pipelines with internally discovered assets. In turn, these will become the therapeutic breakthroughs of the future as the cutting-edge science progresses.”

Sweden’s pipeline is characterized by diversity, led by a large number of smaller biotechs with a collectively broad research focus. In total, Pharmaprojects notes 128 separate Swedish biopharma companies actively involved in R&D. Again, Sweden is fifth on this measure, although the gaps to Germany (135), Switzerland (162), and France (166), are within reach. No single company has more than 12 publicly disclosed assets under active development, with cell therapy pioneer Anocca and the antibody specialist BioArctic jointly leading the domestic charge. These two companies account for just 7% of Sweden’s total pipeline, compared to 22–40% for the top two contributors in the other major European countries.

Oncology is naturally the largest focus of Swedish research, as is the case throughout the pharmaceutical industry. 133 separate programs are targeted against cancer, representing 38% of the pipeline. Neurology (16%) and alimentary/metabolic (13%) are also leading priorities for drug development but fall some way behind oncology. Across all disease areas, Swedish companies are investigating the full range of drug modalities, from small molecules through to advanced genetic medicines. Conventional drug discovery remains the mainstay, although Sweden is well positioned with a growing pipeline of cell (33), gene (20), and RNA-based (7) therapeutics (note these counts are not mutually exclusive).

**Life science investors must be enticed into Sweden**

Despite burgeoning pipelines, Swedish biopharmaceutical companies have been unable to match the level of funding from European peers. Sweden ranks just 11th in terms of financing within Europe since 2015, raising approximately \$2.8bn through venture financing, public offerings, debt placements, and other means. This is under half the total for Danish companies and many times lower than other European countries. In total, Sweden has just a 2% share of all biopharma financing within Europe. This capital constraint is challenging those companies seeking to progress their candidates through clinical development.

Nevertheless, there are some encouraging signals within Sweden. Notably, 2021 was a record year for financing with almost \$800m raised, surpassing the previous peaks of 2020 and 2019. While funding has approximately halved so far in 2022 (data available

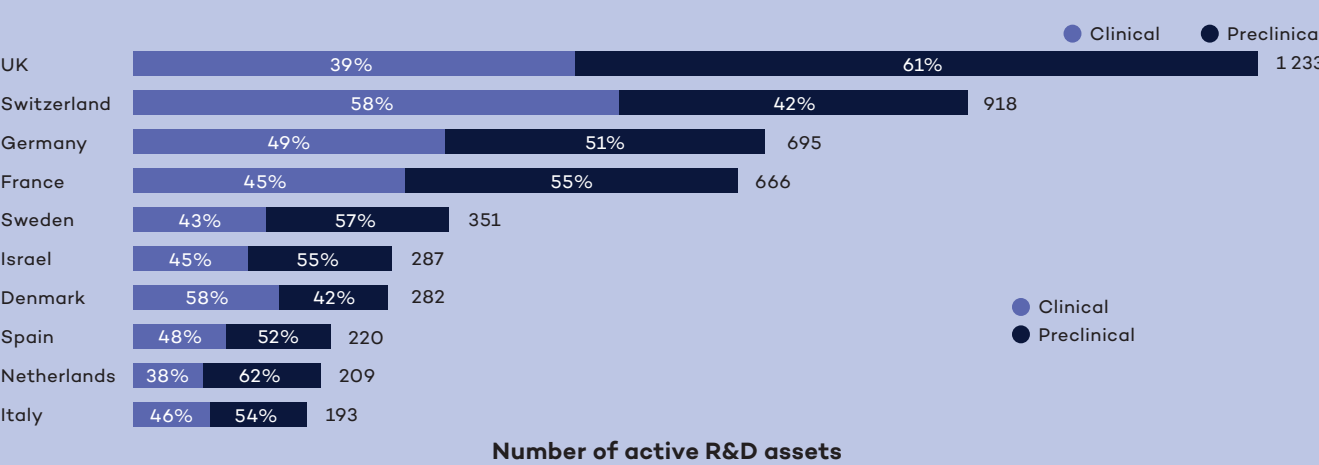
until December 9), this is the result of the wider global biotech downturn and macroeconomic pressures. Regardless of the trend, it is clear that Sweden must come up with creative ways to attract investment into its home-grown start-ups.



**Daniel Chancellor**  
Thought Leadership and Consulting Director, Citeline

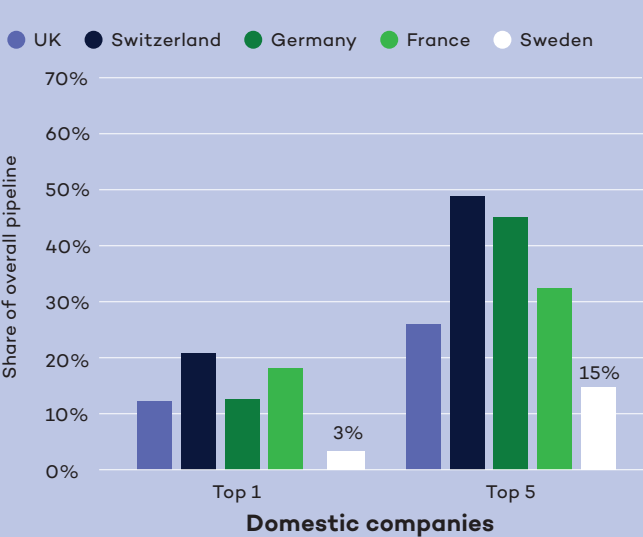
**Note:** This article is provided by Citeline, a partner of the Swedish Drug Discovery and Development Pipeline report. Its findings are based on Swedish and European data from the database Pharmaprojects. The numbers of, for example, active projects and companies in Sweden, differ from numbers given in the rest of the report as this article is based on another data set. One main difference of data sets is that Pharmaprojects maps companies with drug assets disclosed in the public domain, whereas the Swedish pipeline report includes companies at the very earliest stages of drug discovery.

European pharma drug pipelines by country, top ten



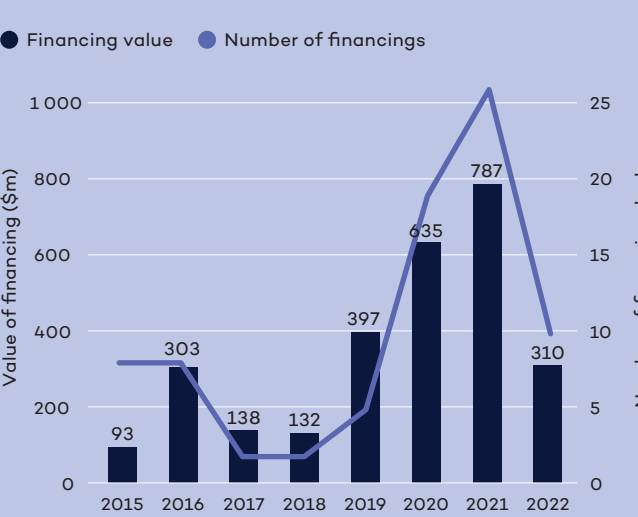
Source: Pharmaprojects, Citeline, December 2022

Leading contributors’ share of biopharma pipelines by country



Source: Pharmaprojects, Citeline, December 2022

Swedish biopharmaceutical financing, 2015–22



Source: Biomedtracker, Citeline, December 2022



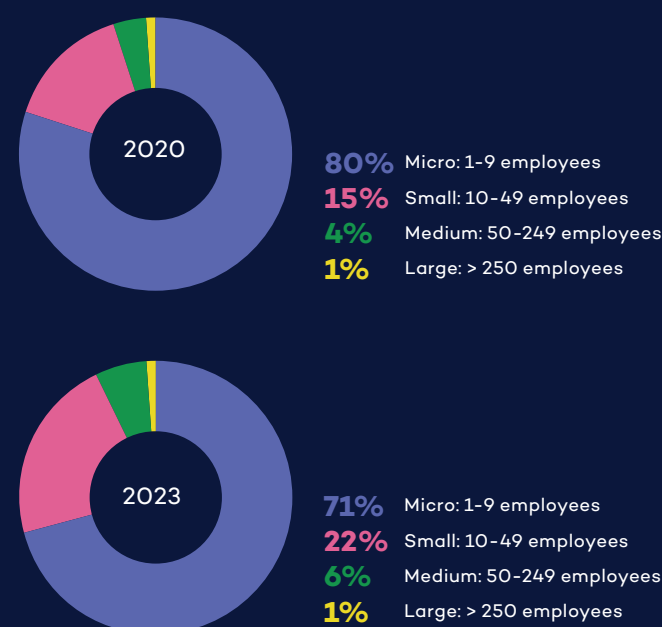
## COMPANY POPULATION

# An ecosystem built on micro-sized companies and academic spin-offs

By analyzing data from 159 pharmaceutical companies headquartered in Sweden, this pipeline report paints a picture of a domestic life science ecosystem mainly active in biotech and pharma with a high number of micro-sized and small companies.

## Company population

To describe the Swedish company population with active drug discovery and development projects, we start by looking at company sizes as determined by the number of employees. The population is dominated by micro-sized companies – 71% of companies have less than 10 employees, 22% of companies have 10-49 employees, 6% have 50-249 employees and only one company has more than 250 employees. We see small changes in company sizes compared to pipeline report 2020: an increase from 29 to 37 small companies, and an increase from 6 to 10 mid-sized companies, whereas the fraction of micro-sized companies has reduced from 80% (2020) to 71% (2023).



## Life science segment and identity

In order to investigate the identity and self-classification of the company population, the companies were asked to choose the segment that best defines their business. Even though all companies herein have been selected to cover pharmaceutical RnD, a slight majority (52%) of the responding companies define their segment as biotech. Almost as many (46%) define as pharma, and three companies as medtech, diagnostics or other, respectively.

Almost half of the companies (46%) relate to multiple segments. The most common combination is biotech and pharma. Nine companies include diagnostics when selecting all relevant segments. Companies defining as biotech cover multiple segments to a larger extent than pharma companies.

## Business activities

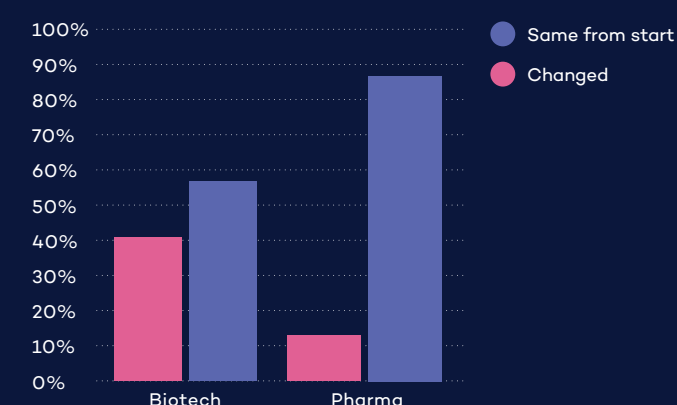
The companies in the pipeline report have been selected based on that they perform pharmaceutical research and development (RnD). To no surprise, 95% of the responding companies reported that RnD was their main activity. Two companies reported that market and sales were their main activity and two companies are mainly providing RnD services\*. Seventeen companies perform their own manufacturing, and 12 companies market and sell their own products.

\*A criteria for inclusion however is that the company performs RnD on their self-owned projects.

## Dynamic nature of life sciences

To understand the dynamic nature of the life science industry, we asked the companies if they have changed business activities since the company was founded. A larger fraction of the biotech (41%) than the pharma companies (13%) reported that they have changed activities since the start. The changes mainly concern expanding into more activities. Changed activity was more frequent among the larger companies. Half of the mid-sized companies have changed activities since the start, and 27% of the small ones. Only 15% of micro-sized companies have changed activities, most probably highlighting the correlation between company age and size.

## Main business activity

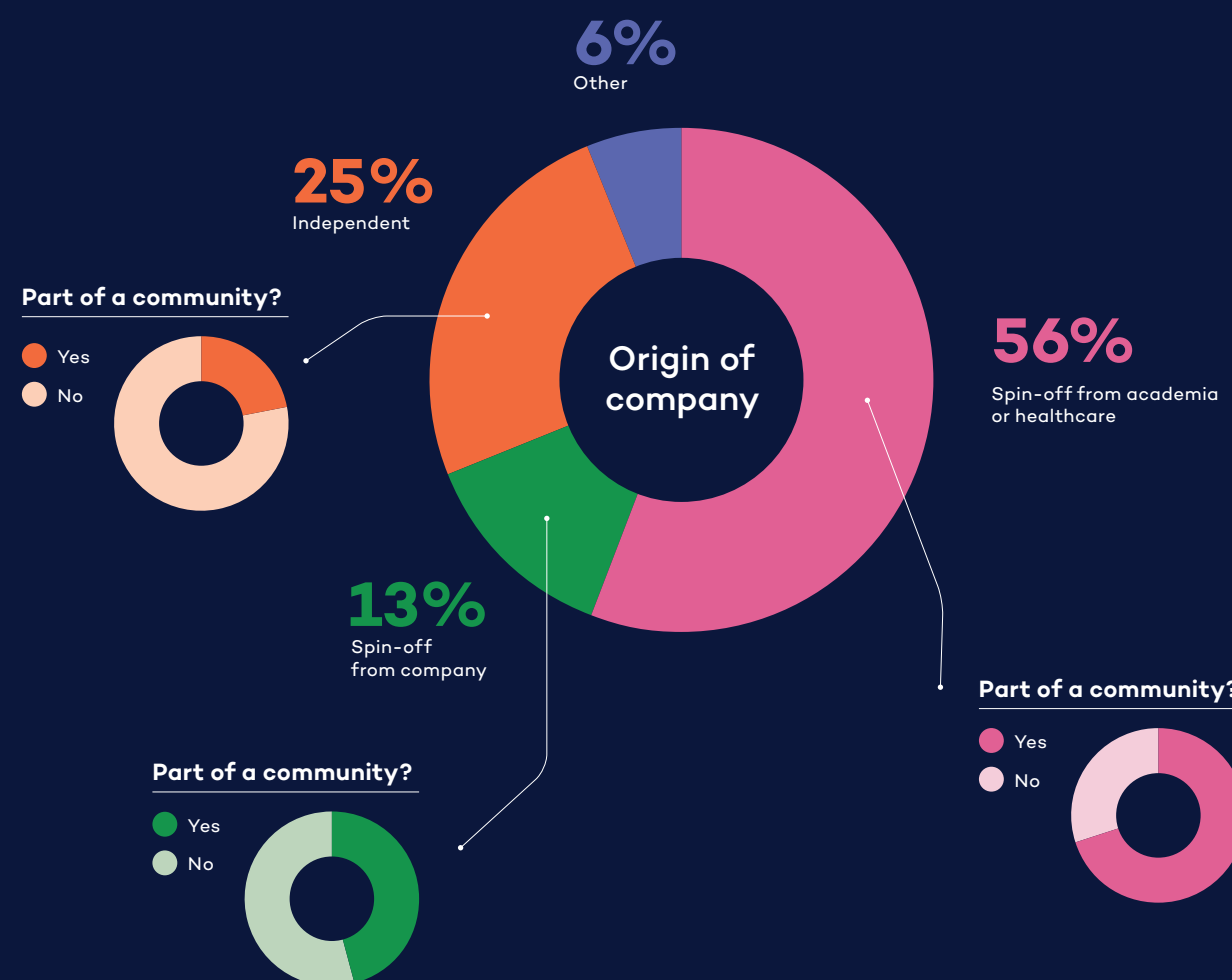


## Company origin and communities

We mapped the origin of companies and their engagement in communities such as incubators, science parks and other structures. More than half of the companies, 56%, are spin-offs from academia or health care, while 25% of companies are founded independently, and 13% are spin-offs from companies. As many as 70% of academic spin-off

companies are part of a community, which often take place in close proximity to academic milieus, while companies with other origins are less present in such communities.

60% of the mapped companies are members of the life science industry organisation SwedenBIO, the main publisher of this report.





## THE SWEDISH STORY

# The foundation of Sweden's life science ecosystem

The Swedish life science ecosystem is built on innovation, solid research capabilities, and vibrant global pharmaceutical companies that once evolved from academic spin-offs.

## Fundamental capabilities

The Swedish life science landscape is built on universities, incubators, life science parks and a variety of companies developing and manufacturing innovative life science products.

Sweden has a long tradition of world-leading academic research within life sciences, accompanied by a life science industry consisting of innovative start-up companies, the pharmaceutical industry, and manufacturing capabilities. Sweden's consistently high ranking in international biotech, tech, and innovation surveys highlights the decades-long construction of the Swedish life science landscape.

The Swedish system is unique in that researchers own the intellectual rights to their findings, which in turn supports the transition from academic findings into start-up companies creating innovative solutions to improve our health.

“Despite being a relatively small country, Sweden has comprehensive fundamental capabilities within life science. These include internationally top-ranked academic institutions, exceptional research infrastructure, high quality healthcare and clinical research, and a flora of life science companies ranging from start-ups to large international pharma,” says Lars Hammarström, director of Health and Life Science Division at Vinnova, the Swedish innovation agency.

He continues: “These capabilities, together with our strong heritage in life science, the collaborative culture of our society, and Sweden's dedication to quality and integrity provide fertile soil in which life science innovation can thrive.”

## Innovative and dedicated life science nation

Sweden ranked first in the European Innovation Scoreboard in 2022. Earlier in 2022, Nature Biotechnology's Worldview national ranking of health biotech sectors ranked Sweden as a leading centre for research and development in biotech, right after Switzerland and before the United States. Rankings

are always subjective, but they do reflect on the dedication Sweden has put into innovation in the life science field.

“Per capita, Sweden can boast with one of the world's most dynamic and productive biotech ecosystems in the world. This is a capacity we have built over decades, something we should be exceptionally proud of, and an asset we need to responsibly foster and prioritize. If we want to stay on top, we need to increase our ambitions and goals for the future,” says Lars Hammarström.

The Swedish government is dedicated to continuing strengthening the life science sector and become a leading life science nation. Sweden's life science strategy focuses on precision, prevention, and sustainability, and naturally contributes to improving health and quality of life, advancing knowledge, and achieving the 2030 Agenda for Sustainable Development. Medical and pharmaceutical products are the second largest export product category in Sweden according to the Central Bureau of Statistics, making the life science industry crucial for the Swedish economy.

More than 80% of Swedish biotech companies are active in international collaborations and 45% of companies have international members in the board of directors according to this report, illustrating that Swedish actors are players internationally. However, only 25% of companies have international investors, opening the door for more international investors.

“It is important to note, that while the rapid development of life science capacity in other countries is a source of competition, it is also an opportunity for Sweden in terms of increased international cooperation and partnership for the future,” Lars Hammarström says.

Sweden's closest neighbors – Denmark, Finland, Norway, and Iceland – form a competitive life science region with healthcare systems of high international standard. Together, the Nordic countries can respond to the ever-increasing global competition in life sciences.



## Teacher's exemption – a Swedish uniqueness for owning intellectual rights

A unique feature of the Swedish life science ecosystem is known as the teacher's exemption, which stipulates that an academic researcher – rather than the university – owns the intellectual property of their inventions. Many Swedish professors and researchers start their own business based on their academic findings, which boosts the start-up community.

The teacher's exemption encourages researchers to start companies, and 56% of Swedish biotech companies are spin-offs from academia. The uniqueness of the Swedish teacher's exemption attracts foreign talent to perform research in Sweden and then start businesses.

The founder and CEO of Lipigon Pharmaceuticals, Stefan K. Nilsson, who has a background in academic research and applied the teacher's exemption when starting the company, says: “The current system relies

on the individual's own interest of commercialization. It is great for the individual who has an interest and drive to make business out of one's research, but it is perhaps not the best way to take care of the full potential of academic innovations.”

The success in commercializing academic innovations and turning them into business cases is reflected in Biotechnology's Worldview Ranking, where Sweden ranks particularly high in the research and translation pillar, based on metrics related to intellectual properties within life sciences. In support of academic researchers getting started with their business ideas, Sweden has a wide network of incubators, offices, and laboratory facilities within university campuses available for rent, several science parks, and soft funding opportunities – all designed for early start-up companies. Start-up companies enrich the Swedish life science ecosystem by bringing innovative ideas and the courage to implement the newest technologies within the life science field. ■

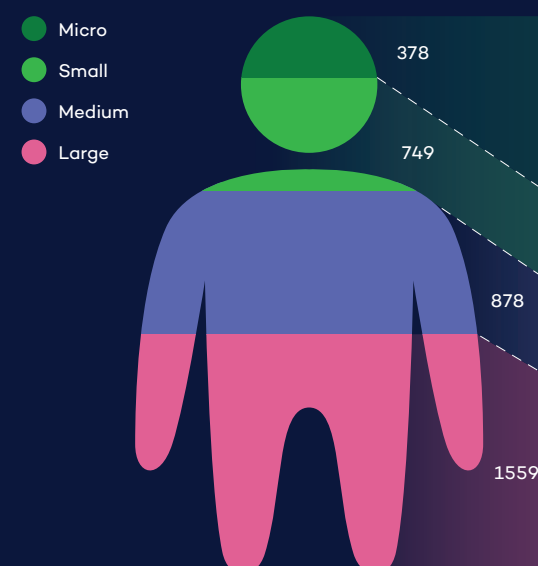


## HUMAN RESOURCES

# Shared resources power the RnD community

Since the drug developing company population is dominated by micro-sized companies with 0-9 employees, there is a large need of supporting infrastructure and know-how.

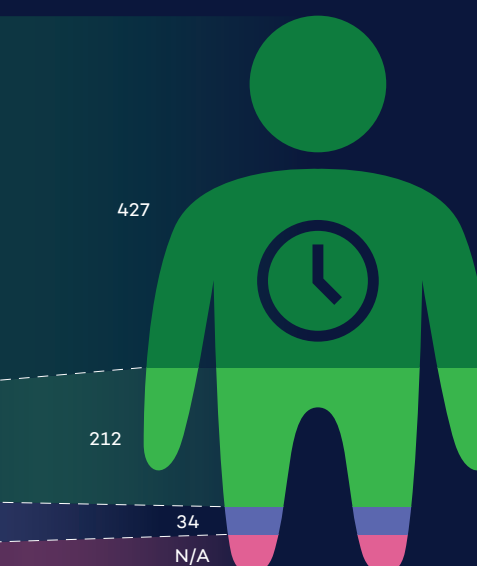
## Employees in total



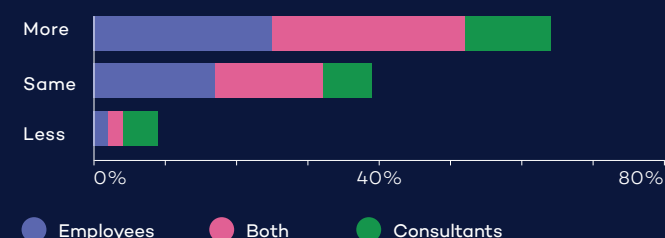
## Number of companies



## Consultants in total

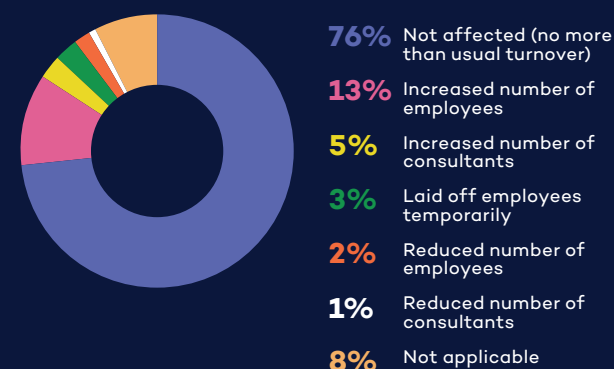


## Recruitment plans ahead



To investigate optimism in the companies, we asked about recruitment plans. 64% of the responding companies planned to expand the workforce by either more employees, consultants or both. 8% of the companies foresee fewer employees and/or consultants during 2023, and 38% plan to maintain existing workforce.

## Effects of the pandemic



We wanted to understand how the human resources of the companies were affected by the pandemic. 73% of the companies stated that the personnel turnover was not affected. 14% of the companies increased either the number of employees, consultants, or both. Only 3% of the companies laid off personnel temporarily. However, several companies reported delays or obstacles in clinical trials due to the pandemic.

## Human resources

Companies included in this report employ 3564 people in total and engage more than 600 consultants (full time equivalents). On average, 75% of both employees and consultants in the micro-sized and small companies are engaged in research and development.

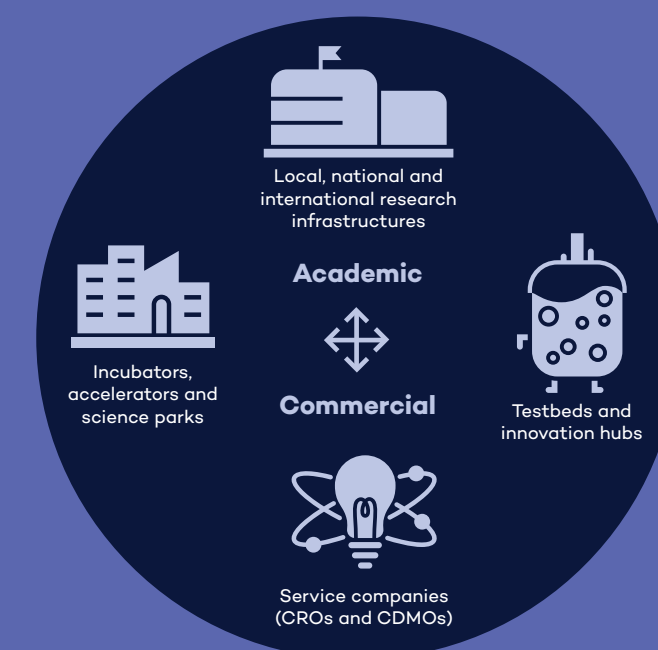
Only one large company within drug development has headquarters in Sweden: SOBI - Swedish Orphan Biovitrum. Out of the 1559 employed by SOBI, 399 are working at the Swedish site.

## International benchmark

As a comparison, global pharma companies employ 76,000 (AstraZeneca), 79,000 (Pfizer), 90,000 (Roche) and 110,000 (Novartis). AstraZeneca has a large RnD site in Sweden which engages approximately 2,800 employees, and a manufacturing site engaging 4,600 persons in Sweden. Pfizer Sweden has 400 employees, Novartis Sweden 220 employees, and Roche employs 160 people in Sweden, but none of these three companies have RnD-sites in Sweden.

# A strong support ecosystem

Sweden's constellation of support organisations enables research and translation at an internationally competitive scale.



**Local research infrastructures** operated through universities offer resources to both research groups and companies. The same applies for the large **national and international infrastructures** (e.g. SciLifeLab, European spallation source ESS, MAXIV, Biobank Sweden) that enable positioning of Sweden on the international arena. Constellations such as consortia and research centers also enable collaborations between industry and academia.

**Incubators, science parks and accelerators** create communities for start-up or scale-up companies and support their growth. **Testbeds and innovation hubs** are offered to produce and test research advancements on a larger scale. They can be found as semi-governmental partnerships with large enterprises (e.g. TestaCenter, NorthXBiologics innovation hub and Bioventure Hub) or through the independent, state owned company RISE (Research Institutes of Sweden).

**Specialized service companies** such as the contract research organisations (CRO) and contract development and manufacturing organisations (CDMO) ensures that methods, instruments and know-how are used at a high capacity at a commercial scale.

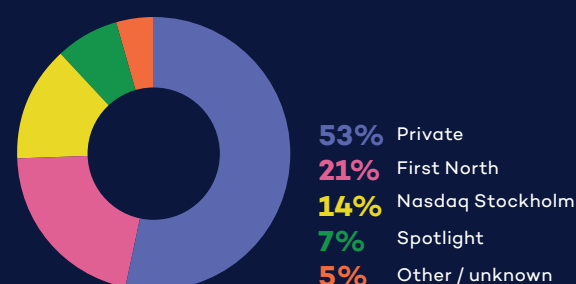


## FINANCIAL SCENE

# Early IPOs an attractive financing strategy

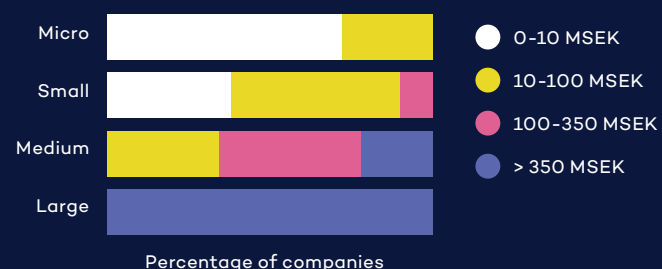
Roughly half of the companies in this report are listed on a public market, and Sweden's second tier stock exchanges are increasingly popular. Securing financing is the main challenge for a majority of companies.

## Private or public

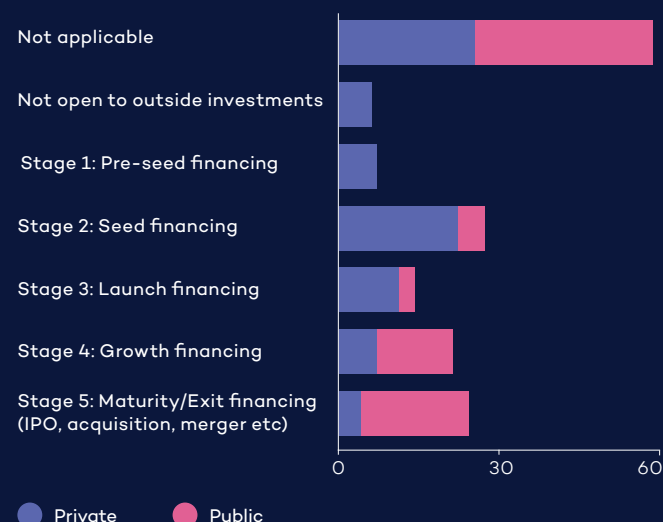


Sweden has two regulated stock markets, Nasdaq Stockholm and Main Regulated Equity. Additionally, Sweden has three multilateral trading facilities, also called second tier stock exchanges, Nasdaq First North Growth Market (First North), Spotlight Stock Market and NGM Nordic SME. Our mapping shows that half of the companies (53%) are private, and the other half (47%) are noted on a public stock market. The most common markets among these drug developing companies are First North (21%), Nasdaq Stockholm (14%), and Spotlight (7%).

## Turnover per company size



## Financial stages



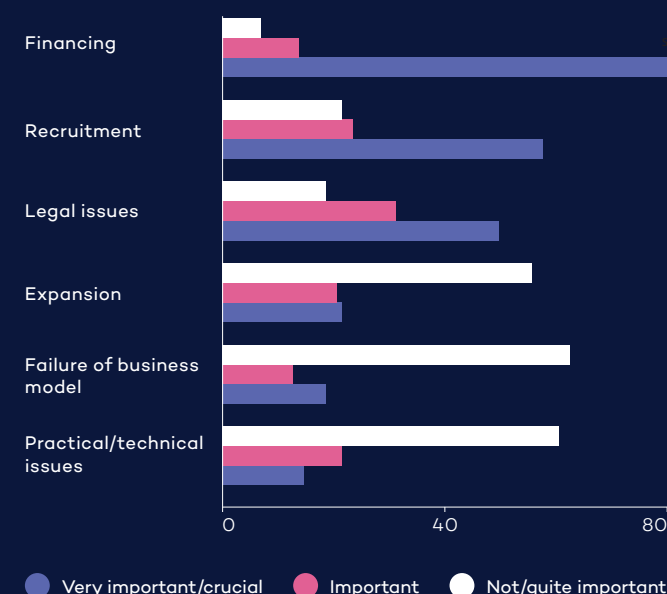
Our mapping shows that the majority of companies in the earliest financial stages are private, but that there exist public companies in all financial stages beyond stage 1. We can see that from stage 4, the publicly noted companies are in majority.

The financial turnover is in relation to the company size, as expected. Most companies report a small or moderate turnover, highlighting that the value of these companies does not lie in their current turnover.

## Export revenue

Medicinal and pharmaceutical products is Sweden's second largest export category (as reported by SCB – Statistics Sweden), creating a substantial value for the Swedish economy. A majority of the export revenue comes from pharmaceutical manufacturing in Sweden by companies with headquarters abroad.

## Challenges ahead



We asked the companies to rank six potential challenges. Out of the six; financing, recruitment and legal issues were ranked as very important or crucial by a majority of responding companies. The other three alternatives; expansion, failure of business model and practical or technical issues were ranked not or quite important by a majority of companies.

## INTERVIEW

### Per Hulthén

Industrial PhD candidate, investigating early IPOs in the life science industry at Chalmers University of Technology.



### Are early initial public offerings (IPOs) unique for Sweden?

We have seen in several countries, across Europe, in the USA and Israel, that Life Science startups are in general more likely to do an IPO than other startups. What is somewhat unique for Sweden is the relative popularity of second tier stock exchanges, such as First North. Second tier stock exchanges exist in other parts of Europe, but they are by far more popular in Sweden than anywhere else.

We can trace the trend of Life Science startups being more likely to do IPOs at least thirty years back. However, the popularity of second tier stock exchanges in Sweden is a relatively new trend, emerging in the last ten years.

### What could be the reason for early IPOs?

Life Science startups require considerable capital and time to become profitable, and acquisitions in general occur rather late, compared to for instance software companies with shorter time to profitability and earlier acquisitions. Going public through an IPO is primarily a financing strategy, as most private investors do not have the capital and patience to finance Life Science startups until they become profitable, which may require a decade or even longer.

### Can anything be said about expected outcome for publicly noted companies?

Stock exchanges have historically played a crucial role in long-term financing of companies, and especially Life Science companies which require more capital and patience than most private investors can provide.

Second tier stock exchange in Sweden have played an important role in providing a long-term funding alternative for startups that have exhausted the patience of private investors. It is not uncommon that Life Science startups are often listed on second tier stock exchanges after having trouble raising a financing round, existing investors have failed to find an acquirer, and the company is too small to list on the first tier stock exchange. For these startups, second tier stock exchange offer a second chance. Some of these startups later become successful, and often transition to first tier stock exchanges or are acquired, while others never become successful.



## PERSPECTIVE: BUSINESS SWEDEN

## Will you join Sweden to pioneer the possible?

Sweden is taking decisive action and inviting the world to collaborate in the collective drive for change. Sweden's innovation-focused, open free-trade economy and inclusive business climate is open for investment, collaborative partnerships, and sustainable growth. To your help is Business Sweden and regional invest promotion partners.

Sweden's life science industry boasts top talent, cutting edge RnD, and highly specialised manufacturing capabilities that help meeting global health challenges. In parallel, data-driven healthcare combined with scientific breakthroughs are revolutionising the way we approach treatment opportunities. Sweden's focus on sustainability, the green transition, innovation, and inclusive workplaces has become a key selling point to attract investments and attention to Sweden.

### The future of life science is digital

This report describes the drug development pipeline, and it is worthy to note that the Swedish pipeline for innovations and solutions in connected health, health-tech, diagnostics, and medical technology is equally strong. There are few large pharma companies who aren't considering a digital component to new treatments and who aren't dependent on data to identify and develop the new treatment.

Sweden's extensive tech ecosystem is playing a significant role in redefining key industries. Stockholm is the second largest unicorn factory after Silicon Valley according to Atomico, State of European Tech 2021 and Sweden boasts over 300 companies in the health-tech sector, many of which already have a substantial international footprint.

### A global perspective

Sweden's booming life science sector is looking to solve the most pressing issues facing healthcare today and the need for global collaboration is essential to make a wider impact. The life science ecosystem in Sweden welcomes the injection of capital investments, alliances for clinical

development and commercial muscles. For this we turn to the international community with an invitation to join the Swedish community.

Sweden is a country with a strong tradition of export and international collaboration. 50% of Sweden's GDP comes from exports and half of the exports come from foreign companies. And with life science being the second largest export category in Sweden, this explains why international relations in this sector is of such importance to the Swedes.

Business Sweden connects international companies with business opportunities in Sweden and provides them with the information, guidance, solutions, and network required to invest in Sweden. In key countries such as US, UK and Korea, Business Sweden has full-time support in life science invest promotion. Locally, Business Sweden has a specialised life-science team who in close collaboration with several regional investment promotion agencies to provide expert guidance and close relationships with the ecosystem and decision makers.

**Charlotte af Klercker**  
International Business  
Development,  
Business Sweden



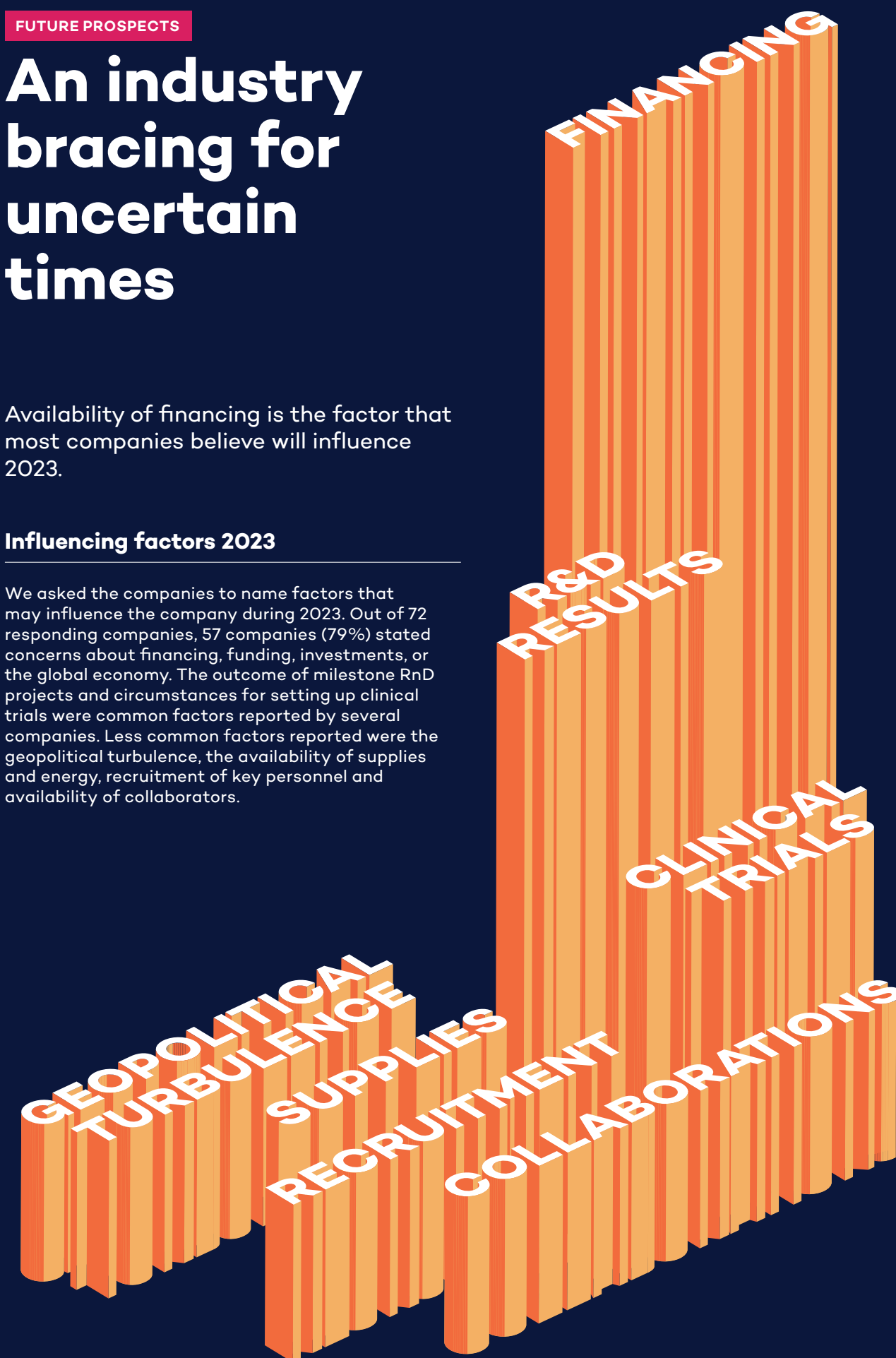
## FUTURE PROSPECTS

## An industry bracing for uncertain times

Availability of financing is the factor that most companies believe will influence 2023.

### Influencing factors 2023

We asked the companies to name factors that may influence the company during 2023. Out of 72 responding companies, 57 companies (79%) stated concerns about financing, funding, investments, or the global economy. The outcome of milestone RnD projects and circumstances for setting up clinical trials were common factors reported by several companies. Less common factors reported were the geopolitical turbulence, the availability of supplies and energy, recruitment of key personnel and availability of collaborators.





## SUSTAINABILITY

# Sustainability as a global competitive advantage

Sweden ranks high in sustainable development goals indices and sustainability is already well incorporated in business, giving Swedish life science companies a competitive edge on the global market as sustainability regulation tightens around the world.

That Sweden and the Nordics stand strong in terms of sustainability hardly comes as a surprise. Finland, Sweden, Denmark and Norway topped the UN Sustainable Development Solutions Network's annual global ranking of countries' sustainable development in 2022, continuing a trend from previous years.

"Sustainability is about long-term value creation. We know that all companies and all activities affect society, positively or negatively. This impact is becoming increasingly important – for authorities, for consumers, and within the financial sector – when we take decisions," Oslo-based Anne Margrethe Platou, ESG analyst at DNB Markets, says.

The ESG criteria – environmental, social, and governance – are objectives that businesses set to manage their sustainability activities and quantify their impact on society and the environment.

Within life science businesses, particularly the S and the G – social and governance – are relevant, as life science companies focus on matters related to patients, health, and medicines, which fall squarely

into the category of social impact. The governance criteria includes issues such as anti-corruption and safe working conditions, which are also at the core of Swedish business ethos.

**"In the past years sustainability regulation has increased in both depth and scope."**

"In the past years sustainability regulation has increased in both depth and scope. Regulation within G – good governance – is about credible, transparent governance structures and is something we are quite accustomed to. However, within environmental and climate issues, regulations have increased, and companies have begun to set very firm environmental and climate targets," Anne Margrethe Platou says.

**"Every investor we're in dialogue with asks questions about sustainability."**

Cecilia Nord, Global Head of Sustainability at Sobi, the biopharmaceutical company focused on orphan diseases with a headquarter in Stockholm, says:

"For a long time, Sweden has had ambitious laws and regulations around issues that fall within the sustainability scope, which means that Swedish businesses have had a lot of time to develop both their thinking and their business models accordingly. The sustainability demands that businesses traditionally face are relatively uncontroversial for Swedish companies."

From a pure business perspective, too, it's a good thing that the Nordic countries already tick a lot of the boxes when it comes to ESG criteria. Governments aren't the only stakeholders who have high expectations of companies in this regard – so do investors, customers, and employees.

"For Nordic companies within life science, sustainability – or having a positive impact on society – is something that's embedded in your business purpose. It is taken for granted. [In the Nordics] we're used to thinking about material issues when it comes to ESG, probably more than traditionally elsewhere in the world. What's new now is that to attract investors the companies have to demonstrate this – not only think that this is a part of our DNA – but actually show, report and highlight it to make themselves attractive," says Anne Margrethe Platou.

Cecilia Nord also emphasizes the importance that sustainability plays in business, and says that biotech companies often rank well in the sustainability indices that investors use when making investment decisions.

"Every investor we're in dialogue with asks questions about sustainability and many international businesses in the biotech sector are good at this, and at finding different ways to showcase their improved sustainability results," Cecilia Nord says.

She concludes: "It's also a way to show that you are, generally speaking, a well-developed, modern, and visionary company." ■

## PERSPECTIVE: VINNOVA

## Vinnova: For a sustainable health system for the future

The Covid-19 pandemic has demonstrated how prioritized health is to the integrity of our society, but has also revealed vulnerabilities in our health system. Healthcare costs continue to rise in parallel to an aging population, the increasing incidence of several diseases, and a lack of equitable access to healthcare and medicine. Innovation is key to overcome these challenges. Yet, if we are to develop a sustainable health system of the future, we need to innovate not just underlying technology, but also how we collaborate, share data, develop policy, and co-create between sectors.

Vinnova is Sweden's innovation agency, providing roughly 350 million EUR in public funding annually to promote research and innovation within Sweden's areas of strength, such as life science. We support innovation on a broad scale, catalyzing development of new technologies, new partnerships, and new arenas for co-creation at the intersection of academia, industry, public sector and civil society.

Vinnova enables innovation that makes a difference, allowing companies to tackle some of the most challenging issues within health and life science. Those challenges include access and utilization of health data, the discovery and manufacturing of advanced therapies and vaccines, novel antibiotics, the implementation of precision medicine, and an increased transition towards preventative measures for maintaining health in society.

As a central component of the Swedish innovation ecosystem, Vinnova provides the life science sector with pre-requisites to make Sweden an innovative force in a sustainable world."

Lars Hammarström  
Director health and life  
science division,  
Vinnova





GEOGRAPHICAL SPREAD

# Innovative hotspots in Sweden

Sweden’s drug-developing companies are primarily located in the country’s main urban areas: the Stockholm–Uppsala region, the Malmö–Lund region, and Gothenburg. A small cluster around Umeå shows promising year-on-year growth.

Number of companies in different regions

	Large	Medium	Small	Micro	Total
East	1	5	23	51	80
South	0	5	8	33	46
West	0	0	6	18	24
North	0	0	0	9	9
Total	1	10	37	111	159

**WEST**

**15%**

**Gothenburg Region**

The presence of global pharma AstraZeneca’s RnD site in the Gothenburg area creates a center of know-how that spurs innovation. Together with local businesses, universities and hospitals, new hubs are created, as exemplified by the GoCo Health Innovation City. Companies within life sciences associated to Bioventure hub and Sahlgrenska Science Park raised more than 2,600 MSEK during 2021. The Gothenburg region handles 27% of Swedish export (all industries) thanks to the large harbor connected to the Atlantic.

**SOUTH**

**29%**

**Malmö–Lund Region**

The south of Sweden is part of the Medicon Valley – the largest Life Science Cluster in the EU – thanks to its close proximity to the Danish life science cluster. With over 65,500 jobs in the private life science industry, 9 universities, and 9 science parks and/or startup environments with a strong focus on life science, the area offers a talent pool characterized by diversity and internationalism. This area also hosts the European spallation source (ESS) and the MAX IV laboratory, the first fourth-generation synchrotron laboratory.

**EAST**

**50%**

**Stockholm–Uppsala Region**

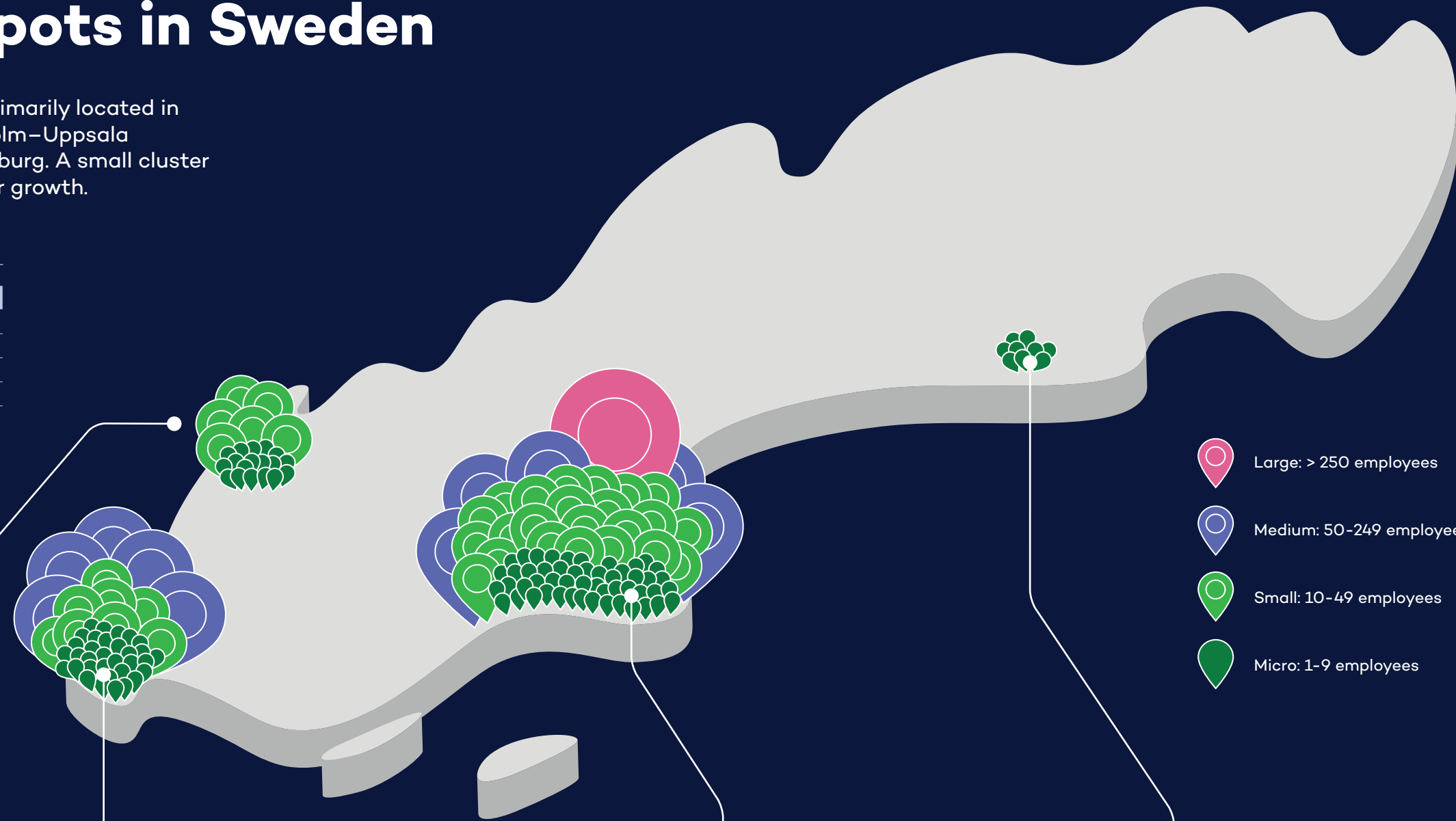
The capital region includes several sites with a high density of companies, 6 universities and 3 university hospitals. Half of all life science employees in Sweden work in the greater Stockholm–Uppsala area. Stockholm Science City reported a company increase by 48% during a ten-year period (2009-2019). The internationally recognized Karolinska Institutet and Karolinska Hospital are the centers of two strong life science clusters; one in the north of Stockholm in Hagastaden and one in the south in Flemingsberg. Uppsala is a city of it’s own built around Sweden’s first university – founded 1477 – today with thriving businesses and research.

**NORTH**

**6%**

**Umeå Region**

Although Umeå is a relatively small life science-region it shows great potential. Umeå Biotech Incubator reports a 17% yearly increase in life science employees over the last five years.



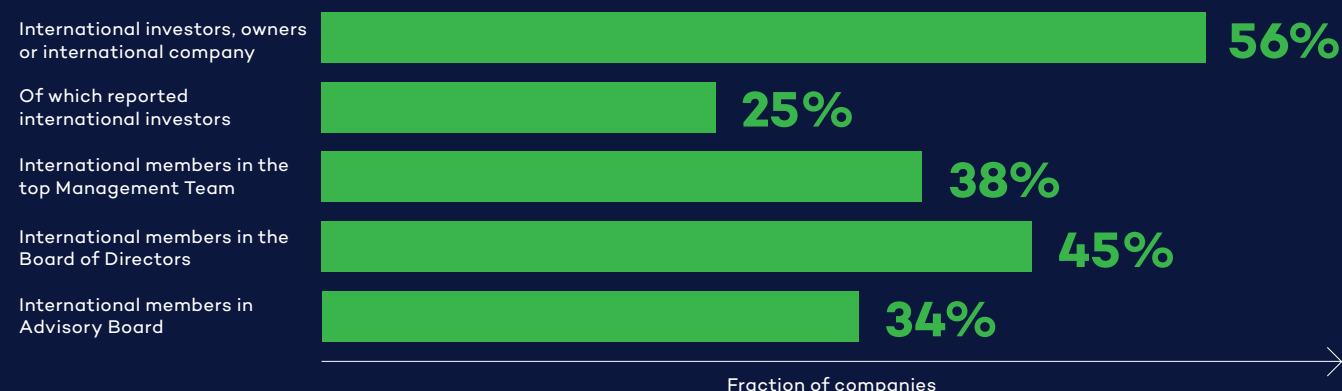


## INTERNATIONAL CONNECTIONS

# Global team players

Swedish companies are highly internationally connected. A majority of companies collaborate or do business across borders, a significant share have international members in key advisory or leadership positions, and many have foreign investors or owners.

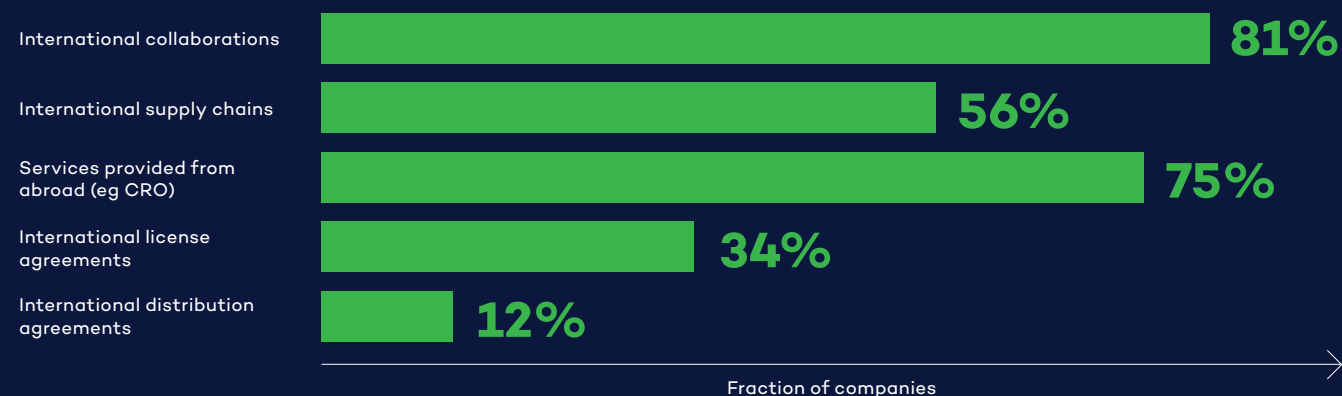
## International funding and leadership



To understand how global these companies are, international funding, leadership, recruitments and activities were surveyed. In total, 107 companies responded to these questions. More than half of the companies, 56%, have international financing including the categories international owners, international investors, part of international group or define the company as an international company.

23% of the companies reported international investors specifically. Almost half of the companies (45%) have international members in the board of directors, ensuring international perspectives on strategic matters. A bit less, 38%, have international members in the top management team, and 34% have international members in their advisory board.

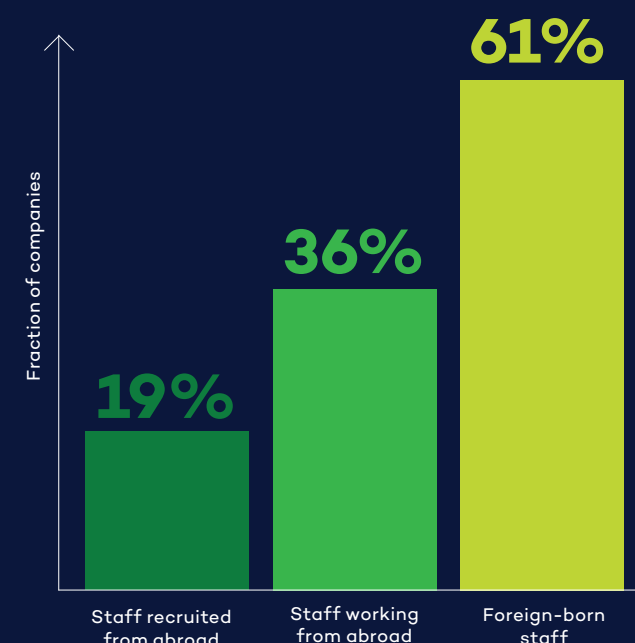
## International activities and dependencies



We see that 81% of the companies have international collaborations with either academic groups or other companies. 75% of the companies rely on services from abroad, such as contract research organisations.

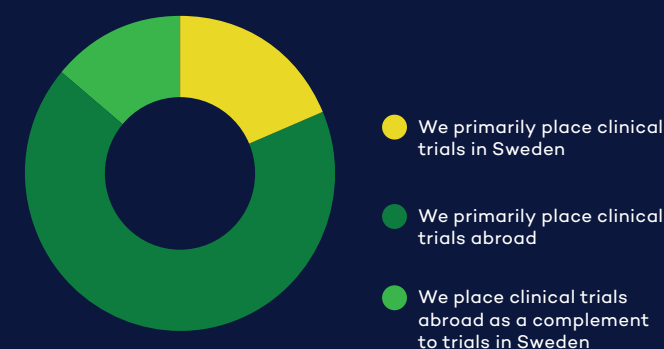
More than half (56%) rely on international supply chains and 34% of the companies have international license agreements. Only 12% have international distribution agreements.

## Human Resources



When looking at the levels of international staff members at companies, we see that 61% of companies have foreign-born staff members, while 19% of companies have recruited staff that have moved to Sweden for the position. 36% of companies have staff working from abroad or at international sites.

## Clinical trials



Based on responses from companies performing clinical trials, N=74 companies.

Clinical trials are a core activity for companies with mature drug development projects. Among the 74 companies that perform clinical trials, 68% primarily do so abroad, 19% primarily in Sweden and 14% both in Sweden and abroad. Several companies commented that specialized clinics and large enough patient populations for the investigated indication cannot be found in Sweden.

## INTERVIEW

### Iris Öhrn

Investment advisor within life science at Business Region Gothenburg.



### Why do you think Swedish life science companies have not attracted more international investors?

This is a complex matter that has many different explanations. Firstly, the companies need to understand the importance of thinking internationally from the beginning. For example, by having international key opinion leaders involved in the projects or by having employees with international connections. The companies also need to be better at approaching foreign investors, keeping them updated and building the relationship long time before they need the funding. At the end of the day investments, as any other business, is a people business. Furthermore, the size of the investment and the stage of the project should also match the requirements of foreign investors, as we are commonly talking about venture capital.

### Which factors are important to attract more international investors to Swedish life science companies?

Born global-attitude is the key. Local investors need to be willing to syndicate and go out to present their portfolio companies. Quality of science and size of the market in our sector is of course a priority for most investors. I disagree with people saying that foreign investors do not hear about Swedish innovations. I think that the Nordic and Swedish innovation branding are well recognized internationally. It is more a matter of having the entrepreneurs themselves going out to show other important aspects in any investments which are the team and its growth ambitions.



## TECH INNOVATION

# Sweden's tech tradition from mining to medtech

In Sweden today, the tech arena is lined with support structures that help start-ups get off the ground. But the tradition of innovation stretches back to an age when mining and forestry offered opportunities and spurred new thinking.

Despite its modest population size, Sweden has brought an impressive array of technological inventions and innovations to market over the past several hundred years. Today, the country consistently tops the European Commission's annual European Innovation Scoreboard, and boasts the highest number of tech unicorns per capita outside of Silicon Valley.

Small, innovative companies finding their footing on the market are aided by a number of support structures, like incubators and national resources offering shared research infrastructures to scientists within industry, academia, healthcare and the public sector.

But to understand the source of the country's innovative power, one must look further back in time.

"It's very clear that we have had a culture of knowledge in Sweden for a long time, which has been underpinned by the welfare system," says Björn Arvidsson, managing director at STUNS Life Science, an Uppsala-based foundation that enhances collaborations between academia, businesses, and public organizations.

A relatively high level of self-determination and intellectual autonomy has also played a part. Property rights were well defined already in the 1600s, encouraging farmers with land tenure to invest in farming techniques. A high literacy level has also contributed – in the 1750's the literacy level in the country was 70-90%. Moreover, a stable society, labor laws, and a fair judiciary system laid the foundation for meritocratic and flat organizational structures, leaving more room for competence rather than social connections to set the stage.

"We also have a strong engineering tradition, to a large extent built on our natural resources – forestry and mining – and the actors in those industries. Companies like ABB, LKAB, Atlas Copco, and Sandvik sprung from that. And in the last hundred years or so, we've had companies like Ericsson, Astra, and Volvo – these industries are the great strength of Sweden."

"This means more people become interested in studying engineering at our universities, which results in an even stronger engineering competence in the country that in turn reinforces the engineering tradition," Björn Arvidsson says.

The story of the ICT-giant Ericsson, founded around 150 years ago, is an apt example of the potential embedded in Swedish engineering and entrepreneurship – and the Swedes' eagerness to adopt novel technologies.

The inventor Lars Magnus Ericsson started manufacturing telephones in 1877 – an invention by Alexander Graham Bell that hadn't been patented in Sweden. Ericsson, together with his wife Hilda Ericsson and business partner Henrik Tore Cedergrén, ran their telephone company so successfully that, by 1886, Stockholm had almost 5,000 telephones – more than any other major world city. Ericsson no longer manufactures phones, but the company is still a giant in the global telecom sector.

There is no shortage of Swedish tech advancements in the medtech area, either. The 1950s saw the dawn of both the ventilator and the pacemaker, and the gamma knife opened new possibilities for brain surgery already in the 60's.

A company that aspires to put the next big thing in cardiovascular care on the market is Scandinavian Realheart – a medtech company in Västerås that develops a completely artificial heart pump.



The telephone tower in Stockholm about 1890, with wires covered in frost. Source: Tekniska museet



A total artificial heart under development in Västerås, Sweden, 2023. Photo: Thomas Finocchiaro, Scandinavian Real Heart AB

Realheart can also showcase a perfect example of the type of public-private collaborations that so often give Sweden's innovation power an extra boost. In 2022, they created a patient simulator together with KTH – Royal Academy of Technology, with funding from the Swedish innovation agency Vinnova. The simulator is unique in Sweden and one of only a handful of its kind in the world – it was modelled after a simulator at the Swiss university ETH Zürich, from where support for the construction of the Swedish simulator was provided. The simulator allows researchers to simulate the conditions of different body sizes which, among other things, enables faster development of heart pumps for women and people with small bodies.

Dr. Ina Laura Perkins, the CEO of Scandinavian Realheart, worked internationally for several years before returning to her native Sweden.

"We are better at taking care of research discoveries that come out of our universities, and packaging them in such a way that they can become products and companies," Dr Ina Laura Perkins says.

"And we have really good tech-transfer offices, and associated incubators like Karolinska Innovation, KTH Innovation, Chalmers Ventures, and GU Ventures. We have this climate where we can take these deep-tech and high-tech research-heavy innovations further. That's why we're better at this than in other countries," she says.

"It's also totally unique for Sweden to have the teacher's exemption (whereby researchers own the intellectual property rights to their findings). In other countries, the research belongs to the universities, but in Sweden researchers can take care of their own innovations," Dr Ina Laura Perkins says. ■



## NUMBER OF PROJECTS

# A sizeable pipeline emerges

The combined national pipeline of Swedish companies is similar in size to one of the big international pharma companies, and is heavily weighted towards early RnD.

## A steadily growing national pipeline

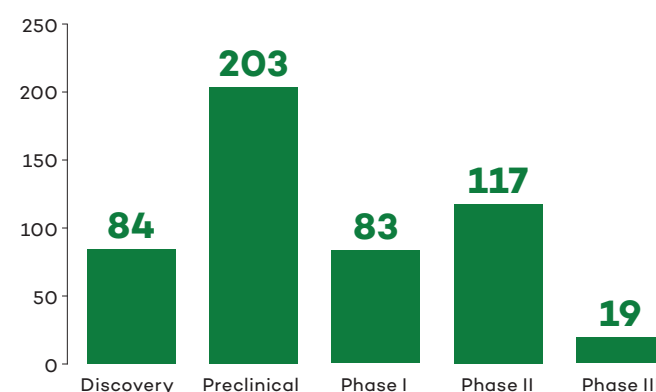
The Swedish Drug Discovery and Development pipeline report has mapped the pharmaceutical pipeline since 2006. We see a steady increase of companies as well as the number of projects mapped. Since 2016, the mapping includes projects and companies in discovery phase. In this edition of the report, 159 companies are engaged in a total of 506 projects. Of these, 221 projects are in clinical phase I, II or III.

## Majority of projects in early phases

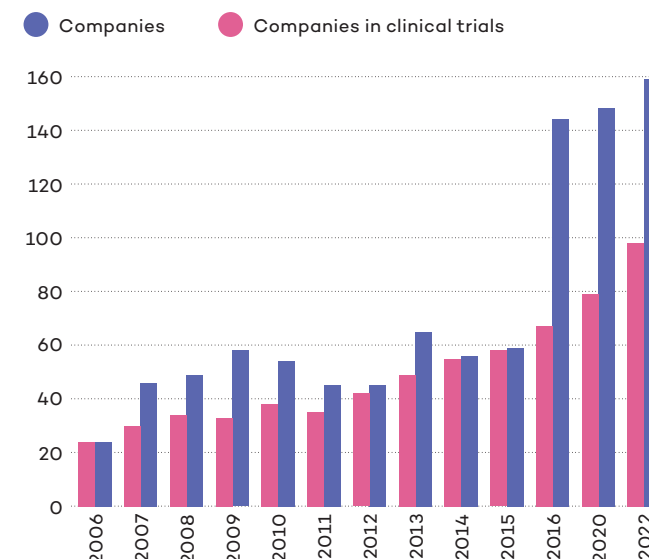
A project is here defined as one investigated therapy per indication. We use this definition to trace phases, progress and success, since one therapy may fail to show efficacy for one indication but succeed in another. The therapies included in the mapping vary from small molecular compounds to whole cells (see page 29), but for simplicity we refer to therapies as drugs. The 506 projects describe 340 unique drugs investigated for several indications.

The Swedish pharmaceutical pipeline projects are largely in early phases. 54% of projects are in discovery or preclinical phase. Among the clinical phases, 16% are in phase I, 23% in phase II and 4% in phase III.

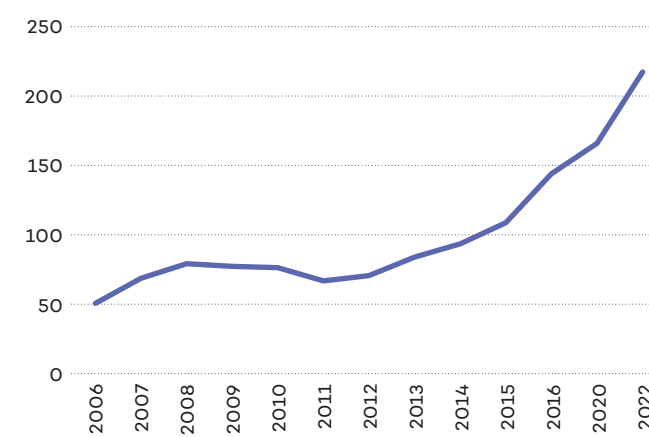
## Total number of projects 2022



## Number of described companies 2006-2022



## Number of mapped projects in clinical trials 2006-2022



## The size of a big pharma company

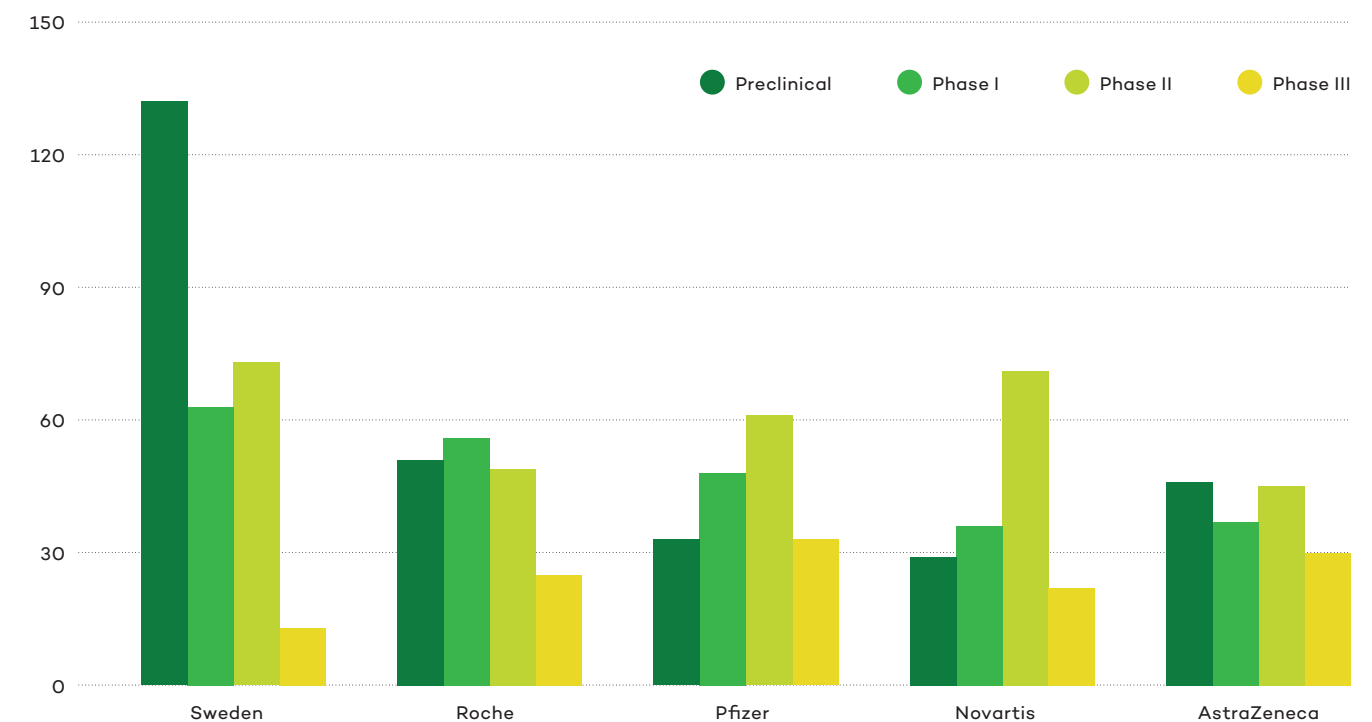
To understand similarities between the Swedish drug development pipeline and pipelines from global pharma companies, we downloaded data from the global database Phmaprojects in December 2022. As this database does not map drugs in the discovery phase, we excluded the Swedish projects in discovery phase.

The combined Swedish pharmaceutical pipeline has a comparable number of drugs in development as some of the largest global pharma companies such as Roche, Pfizer, Novartis and AstraZeneca. In the Swedish pipeline excluding discovery, 47% of the drugs are in preclinical phase, while the percentage of preclinical drugs in big pharma companies are

substantially lower, between 18-29%. We see a common trend of project build-up in phase II, with the exclusion of Roche's pipeline. Phase III drugs among big pharma companies comprise 14-19% of all drugs, while the percentage of phase III drugs is lower in the Swedish pipeline (5%).

The pipeline distribution of big pharma companies may reflect business strategies such as licensing and acquisitions of promising projects or companies in certain phases. The distribution of the Swedish pipeline however, composed of projects from autonomous companies, may reflect the maturity of the Swedish companies and the strong focus on in-house RnD.

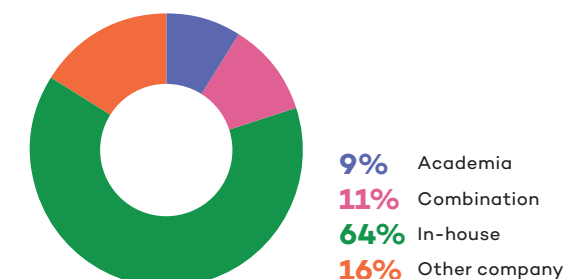
## Sweden gathers 149 drugs in clinical phase I-III, as compared to Roche 130, Pfizer 142, Novartis 129 and AstraZeneca 112.



International data from Phmaprojects, December 2022.

## Origin of idea

The Swedish drug discovery and development pipeline has a strong weight on early phases. We asked the companies wherefrom the ideas for the drug originate, and 64% of the ideas for drugs were developed in-house. 16% of drugs originate from other companies, suggesting that licensing or merger and acquisition deals are minor sources for ideas within Swedish companies. 9% of drugs originate from academia and 11% from combinations of academia and industry, highlighting the importance of industry-academic collaborations.



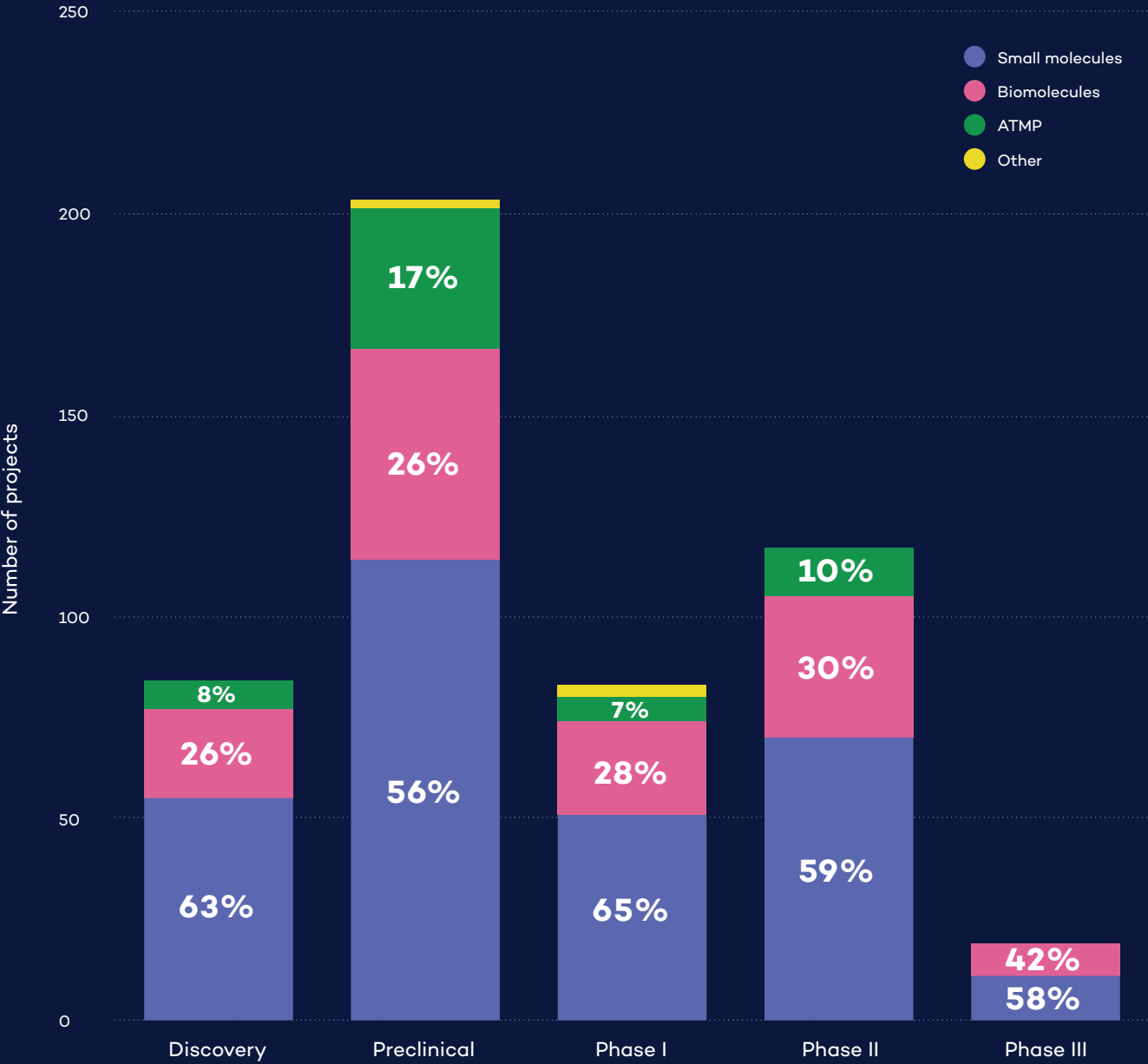
MODALITIES

# What’s cookin’ in the Swedish pipeline?

Biomolecules and advanced therapies are on the rise, but small molecules still hold a majority of the Swedish pipeline.

## Small molecules still rule

The fraction of small molecules has been relatively stable between 50–60% over the last decades. Even though impressive advancements in development and production of biomolecules and advanced therapies have been made, we still see that the small molecules are in majority throughout all phases in the pipeline. The fraction of ATMPs has increased from 8% in 2020 to 12% in 2022.

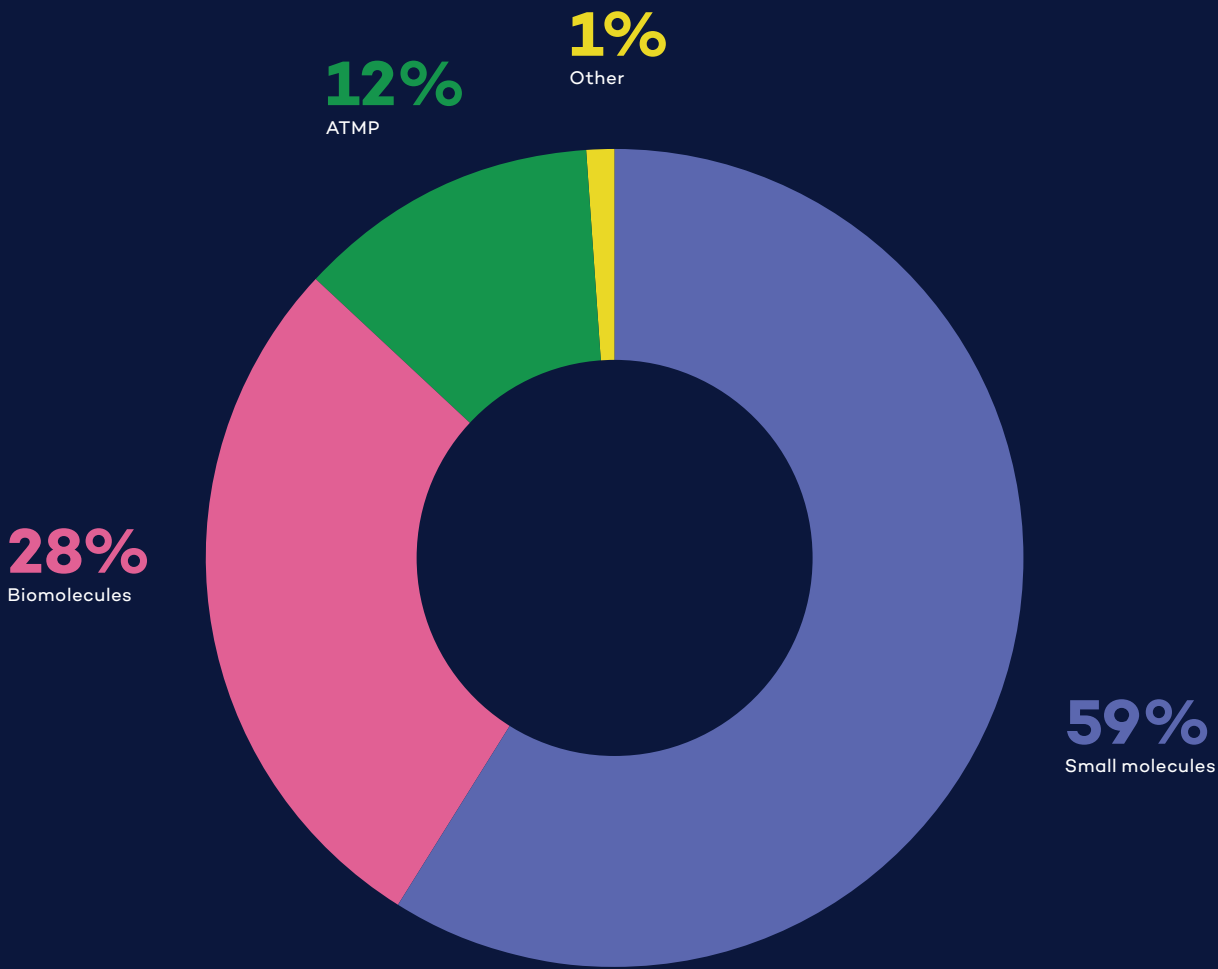


## What kind of molecules are investigated?

The modality of a drug has large implications on many stages of drug development such as formulation, administration, and manufacturing of large quantities of the drug. Generally stated, small and synthetic molecules are possible to scale up and produce in a standardized matter more easily than biomolecules. Advance Therapy Medicinal Products (ATMPs), which is a group of cell, gene and tissue based therapies, are in general patient-specific which further complicates scale-up.

A majority of the Swedish pipeline projects (59%) are based on small molecules. Included in this category are the synthetically manufactured larger molecules such as short peptides and oligonucleotides, which make up 5% of the total number of projects. Biomolecules constitute 28% of the pipeline projects and is the most diverse category. Here we gather modalities such as antibodies, other types of proteins, biologically produced peptides and whole bacteria or yeast cells. The ATMP-classification is standardized based on regulatory directions and constitute 12% of the current pipeline. The category Other contains nanoparticles that often are used in combination with other compounds to enhance bioaccessibility.

CATEGORY MODALITY	NUMBER OF PROJECTS	FRACTION OF PROJECTS
Small molecules	275	59%
Small molecule	275	54%
Peptide (synthesized)	15	3%
Oligonucleotide	11	2%
Biomolecules	140	28%
Antibody (including antibody conjugate)	58	11%
Protein (including protein conjugate)	34	7%
Peptide (biologic)	20	4%
Polysaccharide	11	2%
Biological (Including whole bacteria, yeast, viruses)	9	2%
Biosimilar	4	1%
Vesicle	4	1%
ATMPs	60	12%
Somatic cell therapy	39	8%
Gene therapy	19	4%
Combination product	2	0%
Other	5	1%
Nanoparticles	5	1%
Total	506	





THERAPEUTIC AREAS

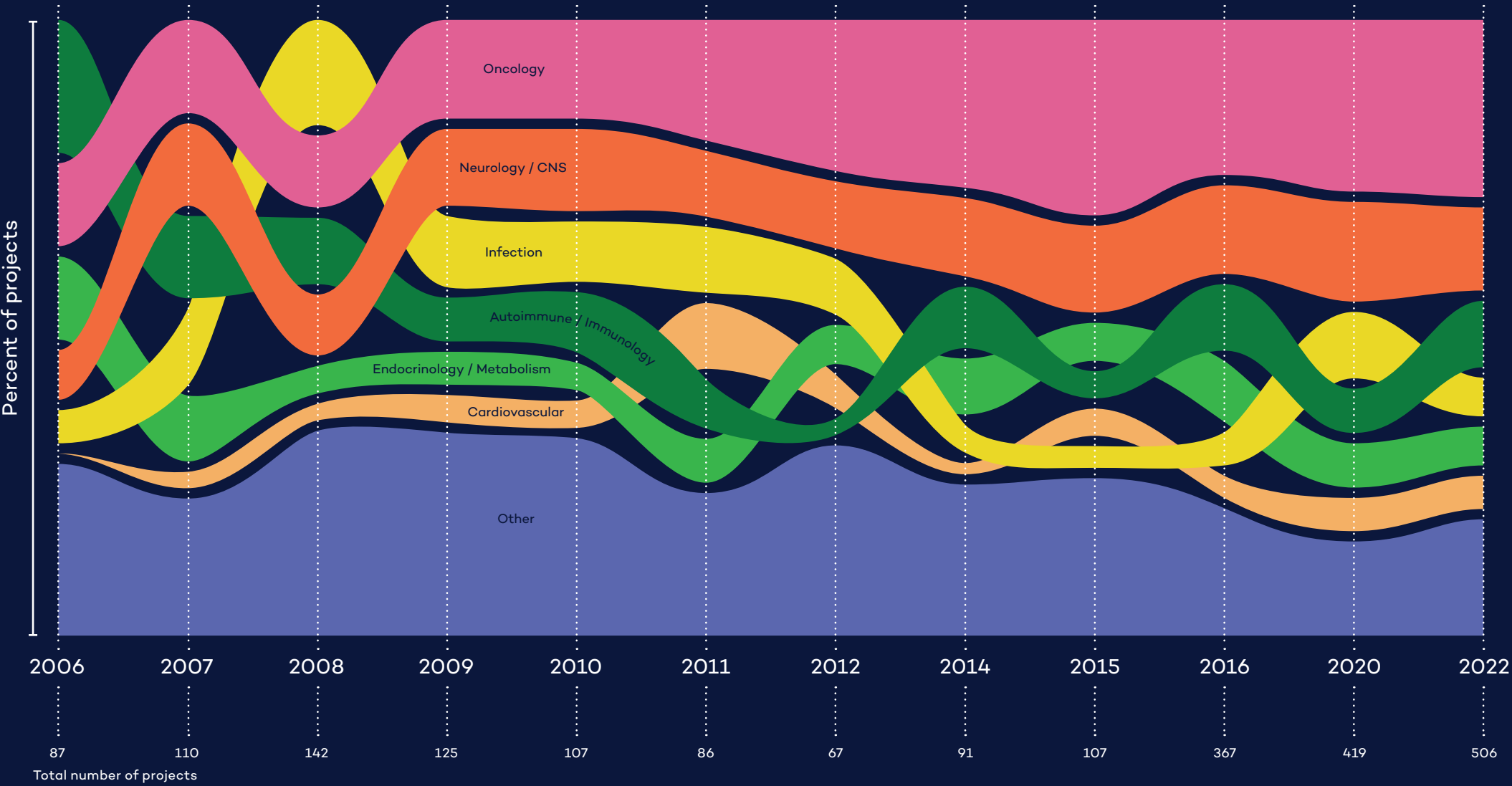
# A stronghold for oncology and neurology

The Swedish pharma industry spans a broad selection of therapeutic areas and indications. Rare diseases and the large disease areas that are common in an aging western population are often targeted.

### Multitude of therapeutic areas

The Swedish pipeline gathers projects targeting hundreds of indications categorized into 19 therapeutic areas. Please see the detailed company list and project list in the appendix for a full overview of therapeutic areas in the Swedish pipeline. Several

companies target rare diseases, but we also see the large disease areas that are common in an aging western population such as cancer, diabetes and neurodegenerative disorders.



Note that the timeline is irregular. See the methods section on page 46 for details on classifications of therapeutic areas.

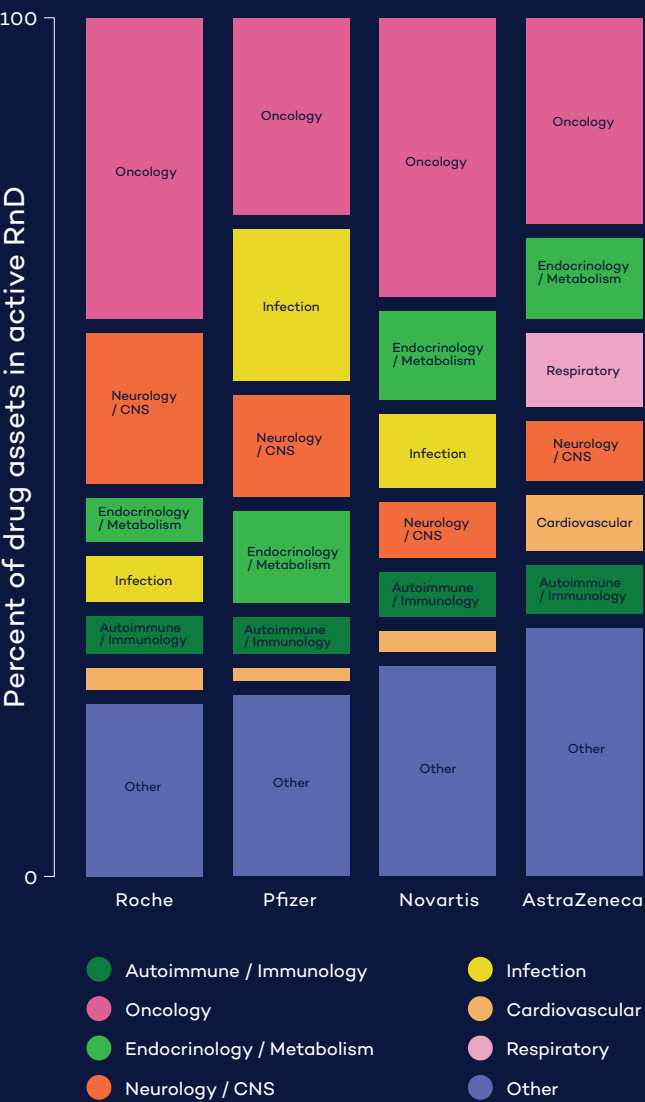
### Oncology and neurology on top

We were interested to see if the relative focus between different therapeutic areas (determined by the relative number of projects) has shifted over the years. The largest area, oncology, including 32% of projects 2022, has held the lead for over a decade. During the same time, projects within neurology and/or central nervous system (CNS) has taken a stable second place, including 16% of projects 2022. Before 2009, the top focus shifted between immunology, oncology and infection.

Below second place, we see that the relative ranking of immunology, infection and endocrinology/metabolism vary between years. This is largely due to that these areas include roughly 10% each of all projects, with slight variations from year to year. We also note that cardiovascular diseases are not a major focus of drug development, including 5% of projects 2022, even though this category is the second most common reason of death in Sweden, after cancers, according to statistics from the Swedish social welfare board (Socialstyrelsen).

### International pharma comparison

We have extracted similar information from Pharmaprojects on four international big pharma companies. We see that oncology has a stronghold on first place, whereas the companies diverge in focus on second place. Roche, like Sweden, has neurology on second place, whereas Pfizer focusses on infection and Novartis as well as AstraZeneca focus on endocrinology/metabolism. Interestingly, AstraZeneca has respiratory diseases on third place, which is a therapeutic area below the top six for the other investigated companies.



Data extracted from Pharmaprojects December 2022.

PHASE PROGRESSION

# Pipeline progress since 2020

A comparison of data collected in 2020 and 2022 reveals the transition rate of projects in the pipeline, showcasing the progress of Swedish drug discovery and development projects.

### Progression rates since 2020

We tracked the progression of projects by comparing the current pipeline projects to the projects in the 2020 pipeline report. Out of the 420 projects reported in 2020, 296 (70%) were also reported in this pipeline report. Of these, 216 are still in the same phase, whereas 81 projects have advanced in the pipeline. Using these 81 projects, we calculated progression rates across the pipeline. Note that a progression rate is highly dependent on the time interval, and the 2.8 years between data collections in first quarter of 2020 and last quarter of 2022 is a very short time in relation to drug development.

We see that 21% of discovery projects have advanced into preclinical stage within three years. Note that the definitions of discovery and preclinical stages are semantic. From the preclinical stage projects, we see that 17% advance to phase I within three years. 27% of the projects advanced from phase I to phase II, and 6% are traceable to have advanced

from phase II to phase III. Out of 23 projects in phase III in 2020, 52% exited phase III successfully within three years. Read more about these phase III exits on page 34.

### Phase transition success rate

The metric phase transition success rate measures phase progression in a time-independent manner, as reported in *Clinical Development Success Rates and Contributing Factors 2011–2020* (published by BIO). The success rate relates the number of project advancements to the number of projects that left a certain phase, either by advancing or by suspension. (Suspension includes all potential reasons for a project to be discontinued.)

With this metric, we see that 35% of projects in discovery advance to preclinical phase, and 39% advance from preclinical to clinical phases. We note that 55% of phase I projects advance successfully, 28% of the phase II projects, and 67% exit phase

III successfully. Note that these metrics are based on a small number of projects. However, when comparing to calculations based on thousands of drug transitions over almost a decade similar success rates are presented (see textbox).

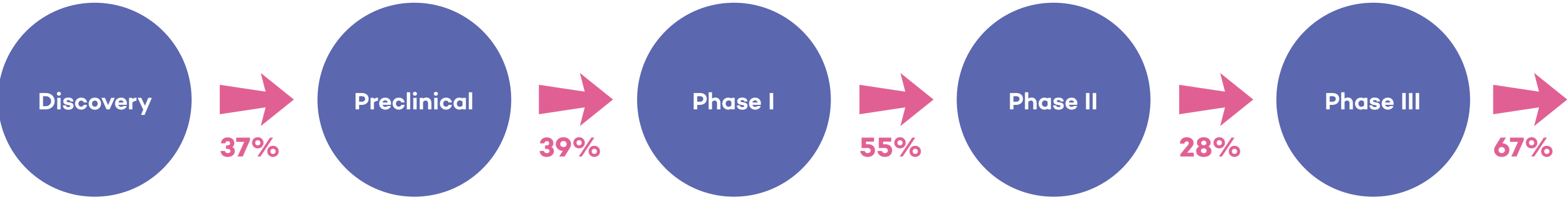
We can conclude that the transitions within the Swedish pipeline are of approximate equal success rates as that of global pharma, even though the measure does not take into consideration projects that remain (too) long in a certain phase. We calculate an approximate success rate of 35% from discovery to preclinical phases between 2020 and 2022 data collections. This phase transition rate is unique for our report, as other sources does not map discovery projects. ■

### INTERNATIONAL COMPARISON

- Relatable transition success rates, based on almost 13,000 transitions in 1,800 companies globally:
- 52% from phase I to Phase II
  - 29% from Phase II to Phase III
  - 58% from phase III to approval

As reported by *Clinical Development Success Rates and Contributing Factors 2011–2020*, BIO.

### Phase transition success rates



PHASE 2020	TOTAL	STILL IN PIPELINE 2022	SUSPENDED (NOT INCLUDED IN PIPELINE 2022)	STILL IN SAME PHASE 2022	ADVANCED IN PIPELINE	PROGRESSION RATE (ADVANCEMENTS / TOTAL NUMBER OF PROJECTS 2020)	PHASE TRANSITIONS N (ADVANCEMENTS + SUSPENSIONS)	PHASE TRANSITION RATE (N/TOTAL)	PHASE TRANSITION SUCCESS RATE (ADVANCEMENTS / N)
Discovery	85	52	33	35	18	21%	51	60%	35%
Preclinical	165	121	44	90	28	17%	72	44%	39%
Phase I	66	51	15	29	18	27%	33	50%	55%
Phase II	81	65	16	56	5	6%	21	26%	24%
Phase III	23	7	16	6	12	52%	18	78%	67%
TOTAL	420	296	124	216	81	19%			



## PHASE III EXITS

# What comes after phase III

Just over half of the projects that were in phase III in the 2020 pipeline report have made successful exits.

## Exits from phase III

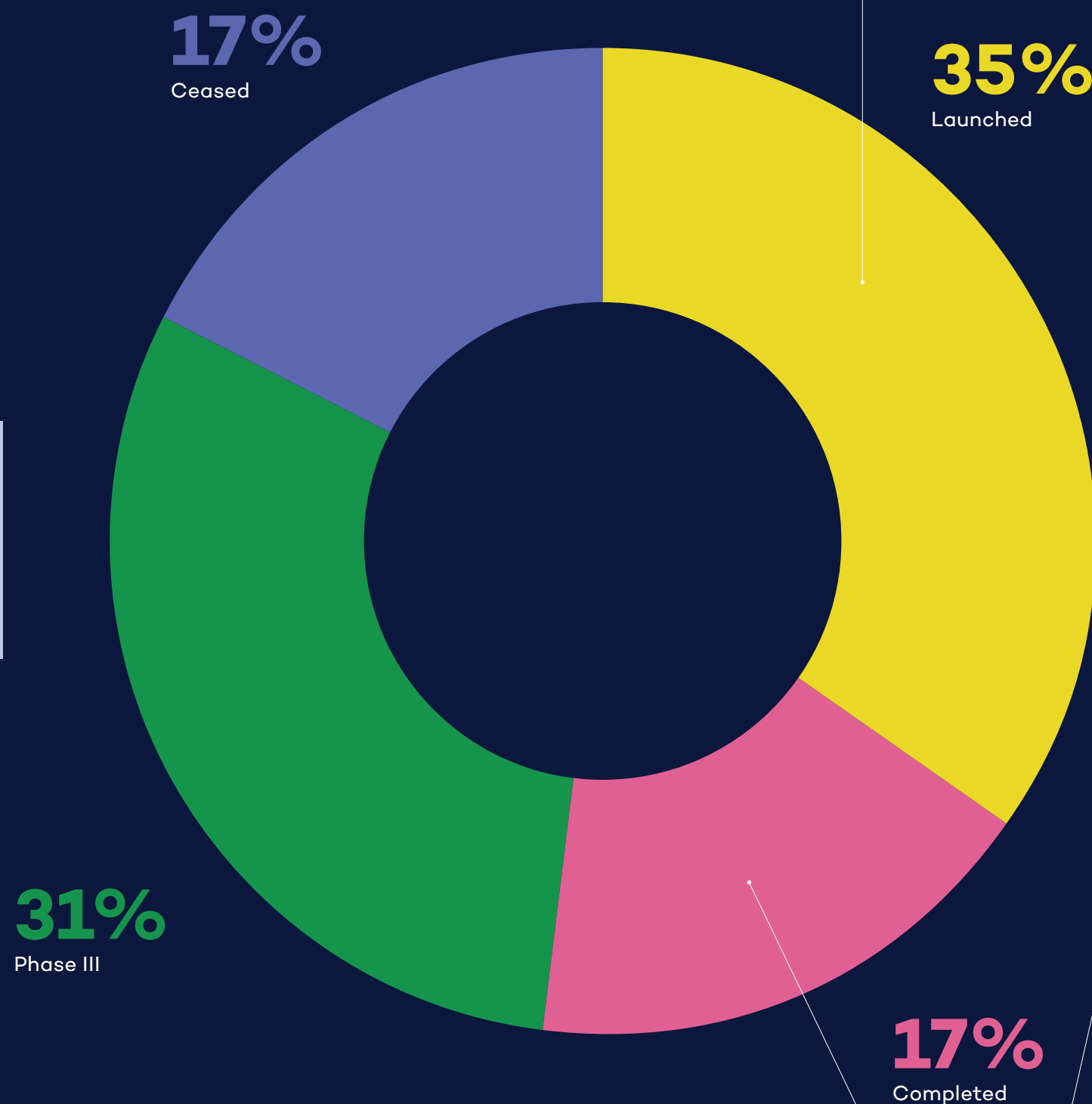
The pipeline report maps active projects in the drug development pipeline, meaning that when a project exits phase III, it is no longer included in the mapping. But these projects are of course of particular interest so their status were mapped through public sources such as websites, press releases and regulatory authorities.

Out of 23 projects in phase III trials in 2020, we were able to trace that eight projects (five drugs) have been launched. Four projects are completed in phase III but not yet launched, meaning that they are in a regulatory pathway. See description of these successful projects on the right. Seven projects are still in phase III trials. Four projects have been removed, suspended or ceased.

## FACTS

In 2022, 19 projects were reported to be in phase III trials:

- 7 are new compared to the project list 2020
- 5 have transitioned from phase I or phase II since 2020
- 7 projects from 2020 remain in phase III



## Launched projects since 2020

Eight projects from five companies have been successfully completed and the therapies have been approved.

**1) Lecanemab (BAN 2401) from Bioarctic** in partnership with Eisai/Biogen is an antibody for treatment of early Alzheimer's that is approved in both EU and the US (as Leqembi).

**2) Avatrombopag from SOBI** is a small molecule for the treatment of chemotherapy-induced thrombocytopenia and launched as Doptelet®.

**3,4,5) Isicort (dexamethasone) from Acucort** is a small molecule compound that has been approved for treatment of three separate indications; allergy, croup as well as chemotherapy-induced nausea and vomiting. Besides these indications, the drug has shown efficacy for Covid-19 related breath insufficiency. The compound is delivered as an oral film and is now marketed as Zeqmelit™.

**6) Xlucane™ (ranibizumab) from Xbrane Biopharma** is a biosimilar for the treatment of wet age-related macular degeneration.

**7) Tarpeyo/ Kinpeygo (budesonide) from Calliditas Therapeutics**, for treatment of IgA nephropathy. Tarpeyo is approved under accelerated approval by the FDA in the US and Kinpeygo is granted conditional marketing authorization by the European Commission.

**8) Melflufen from Oncopeptides** is a peptide for the treatment of multiple myeloma, launched in the EU under the name Pepaxti®.

## Completed in phase III but not yet launched

Four projects from four different companies have finalized their phase III studies. All of these projects are reformulations of known substances.

**1) CAM 2038 (buprenorphine) from Camurus** is currently under review in the EU and Australia as an extended indication to Camurus' launched product Buvidal® to include treatment of chronic pain, adding to the current indication of treating opioid dependence.

**2) Sumatriptan from Klaria** for treatment of migraine is currently under review in the EU.

**3) AKP01 (Calcipotriol) from Lipidor** is for treatment of psoriasis.

**4) MOB-015 (Terbinafin) from Moberg Pharma** is for treatment of nail fungus.

## HIGHLIGHTS

# The report in short

Selected highlights from the 2023 Swedish Drug Discovery and Development Pipeline report paint a picture of a vibrant life science ecosystem.

## 56%

of Swedish drug developing companies are spin-outs from academia or health care.

## 75%

of the personnel in small and micro-sized drug developing companies are engaged in RnD.

International clinical trial sites and service providers are attractive for Swedish companies.

## EXAMPLE

### Bioarctic – living the Swedish story with success

One of the most recent launches, Lecanemab, highlights a story following the textbook example of a successful academic innovation, translated into a business product with a potential to bring value to thousands of patients.

Bioarctic AB, in collaboration with Eisai Inc. and Biogen, was in January 2023 granted approvals for the company's first product, Lecanemab (BAN 2401), in both the US and the EU. This success is due to hard and ingenious work by the company's founders, Prof. Lars Lannfelt and Dr. Pär Gellerfors, and the combined efforts from research and clinical teams in the three companies.

Bioarctic was founded 2003, based on the academic discoveries of the Arctic mutation\* at the Karolinska Institutet. The company went into collaboration with Eisai Inc. in 2005 and later, in 2014, the company Biogen entered into the collaboration. Discovery and preclinical research were performed during the years 2005-2012 followed by clinical trials during the years 2013-2022.

\*The Arctic mutation causes an autosomal dominant disease with clinical picture of typical Alzheimer's disease.

The size of Sweden's combined clinical pipeline is equal to the pipeline of one of the big international pharma companies.

Sweden's stronghold in oncology and neurology has remained stable for over a decade.

The fraction of ATMP projects is increasing, but small molecules are in majority in all stages of drug development.

Most companies are concerned about financing in the present economical climate, but a majority plan to recruit during 2023.

## PERSPECTIVE: SWEDENBIO

## Strengthening the industry

When I joined the life science industry during the 90s, Sweden had two big pharma companies operating at multiple sites in the country. That strong dominance is long gone, but the legacy remains.

A striking finding in the current pipeline report is that the collective project portfolio of the Swedish life science industry adds up to the same volume of projects as that of a big pharma company's pipeline. It also reflects the same type of diversity in terms of therapeutic areas, modalities, and distribution from early discovery up to late phase clinical studies.

The latest success story from our community was the progression of BioArctic's Alzheimer drug Lecanemab in phase III with a positive outcome – a first-in-class asset from the Swedish smorgasbord of projects and a true achievement. Add to that a competitive target and a high unmet medical need to further emphasize its importance. This is a story that we as a nation should be proud of, and also learn from. The project stems from solid academic research, it was further amplified by an industrial research effort, and backed by a pharma partner that took the drug through clinical studies.

Continuing the big pharma analogy, there is one aspect where the comparison is failing. The compounds and projects in phase II are struggling to make the transition to phase III. The report does not give any reason why our national pipeline is stuck at this stage, but plausible suggestions are a lack of funding to proceed, or lack of strong data to support further development. All development pipelines suffer from attrition and we have to face that our national pipeline does as well – but we need to make sure that the most promising assets get enough funding for studies supporting registration. The financing for this is not available in Sweden, and we need efforts on all levels to bring in international investors.

From the data generated in our report we can observe a tendency towards company growth as several entities have increased the number of employees. We sense that the Swedish biotech sector as a whole is ready to take a leap forward, towards growth. The community has demonstrated that it possesses both competence in drug development and the capacity to innovate. Now is the time to secure funding to strengthen the industry.

Jessica Martinsson  
CEO  
SwedenBIO





FOCUS: ORPHAN DESIGNATION

# Breaking novel ground

An orphan designation is an incentive to drive innovation towards rare diseases that lack approved efficient treatments. When a drug is granted an orphan designation, it receives assistance in a regulatory protocol as well as market exclusivity for a set time frame.

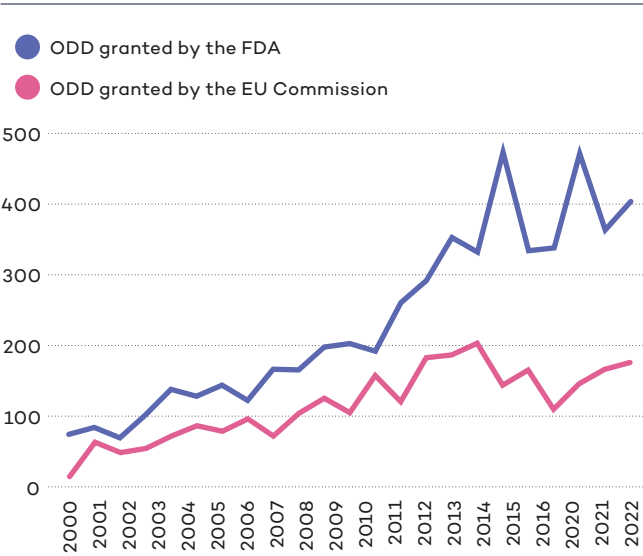
### Attractive incentive

In order to understand the attractiveness of the incentive, we extracted information from regulatory authorities in the US and EU. According to the US Food and Drug Administration, there is an increase of granted orphan drug designations (ODD), but in the EU the trend appears to level out, according to the European Medicines Agency EMA. However according to Pharmaprojects, the absolute numbers of drug development projects in the US and EU evolve in a similar pattern, indicating that the orphan designations are a relatively stable fraction of total projects. When focusing on Swedish projects being granted for ODD, the numbers vary largely between years, with a record of 16 Swedish projects being granted ODD in the US during 2022.

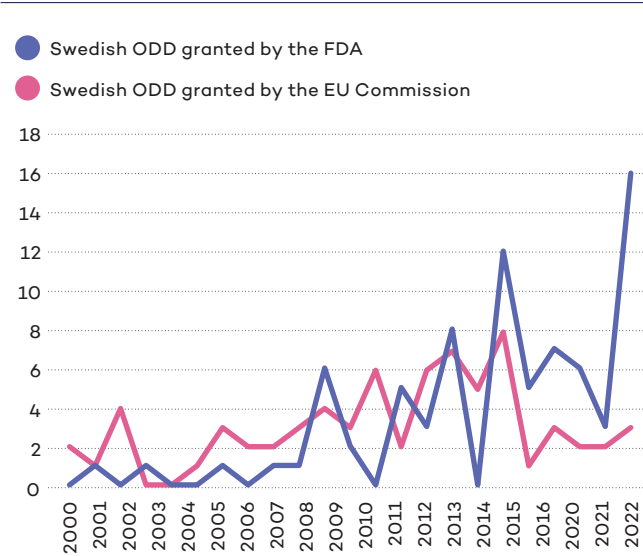
### Orphan designations in current pipeline

In our data collected for the pipeline report we note 131 projects intended to treat a rare condition. Of these, 52 projects (40%) have received an ODD. In the pipeline report 2020 there were 110 projects intended to treat a rare condition, whereof 39 projects (35%) received an ODD. 78 projects for rare diseases from 2020 are also active 2022, whereas 53 projects are new since the 2020 mapping. 32 projects from 2020 were discontinued and three drugs to treat rare diseases have been launched since 2020.

All ODD granted in EU or US



ODD granted for Swedish projects in EU or US



FOCUS: REFORMULATIONS

# Reinventing proven compounds

A majority of the projects that succeeded phase III since 2020 are reformulations of previously known compounds, indicating a fast track to successful exits.

### Development shortcut

Reformulating an existing drug gives developers a head start, as opposed to developing a whole new drug. It is an opportunity to introduce a product that has an established safety and efficacy profile, avoiding the significant development outlay associated with the extensive preclinical and clinical testing that would be required for a new chemical entity. It may also be seen as an improvement on the current standard of care, further enhancing its commercial attractiveness.

### Enhanced uptake

Reformulation can be used to enhance solubility, to improve absorption, or to boost the stability of a drug product formulation. It may also change the route of administration. Creating a version of an existing drug that is more convenient and easier to use for the patient increases quality of life and/or boosts

adherence. Before putting a reformulated drug on the market, it must be proved to be bioequivalent to existing drugs. This requires clinical studies, but often these are smaller and quicker than for new chemical entities.

### Reformulations in current pipeline

In this report we see 25 companies that focus on reformulating known drugs into new innovative formulations, leading to different administration routes or creating different modes of release into the body. Most companies focus on reformulating small molecules, but a few companies are also working on formulations for biomolecules.

COMPANY	DELIVERY ROUTE	DELIVERY TECHNOLOGY
Affibody	Injectable	Small molecule conjugated to protein
Ascelia Pharma	Oral, swallowed	Reformulating solutions to tablets
Calliditas Therapeutics	Oral, swallowed, buccal; Rectal	Enteric-coated, delayed release
Camurus	Injectable, subcutaneous	Gel; Depot; Extended release
DexTech Medical	Injectable, intravenous	Small molecule conjugated to dextran
Disruptive Pharma	Oral, swallowed	Porous nanoparticles
Dizlin Pharmaceuticals	Injectable, intravenous	Portabelt belt pump
Double Bond Pharmaceutical	Injectable, intravenous	Encapsulating; polymer
Emplicure	Tablets; Capsules; Granules; Patches	Nanoparticles; bioceramics
Empros Pharma	Oral, swallowed	Fixed dose combination; Modified release
Klaria	Oral, swallowed, buccal, sublingual	Film, rapidly disintegrating
Lidds	Injectable, intratumoral	Paste; Depot; Controlled-release
Lipidor	Topical, skin	Spray
Masker MedTech	Inhaled, transnasal	Powder, nebulized
Moberg Pharma	Topical	Suspension
Nanexa	Injectable, subcutaneous	Depot; Controlled-release
Orexo	Oral; Inhaled; Transnasal; Topical	Powder; Patch; tablet; Controlled-release
Quiapeg Pharmaceuticals	Injectable, subcutaneous	Pegylated; Controlled-release
Redwood Pharma	Topical; Ophthalmic	Gel; Controlled-release
Spago Nanomedical	Injectable	Nanoparticles; Conjugate; radionuclides
Synartro	Injectable, intra-articular	Fixed dose combination; Modified-release
Vicore Pharma	Inhaled, pulmonary; Oral	Controlled-release
Vivesto	Injectable, intravenous	Nanoparticles; Modified-release
Xbrane	Injectable, intravitreal	Pegylated (proteins); Biosimilars
Xspray Pharma	Oral, swallowed	Nanoparticles

FOCUS: ATMPs

# ATMP by the numbers

Since the first advanced therapeutic medicinal product (ATMP) was approved in the US in 2003, many more have reached the market addressing unmet health needs. But accessibility and cost remain a challenge.

ATMPs have the potential to offer a durable, life-changing therapeutic response for patients who may have few or no alternative treatment options.

However, they are also associated with higher upfront costs to healthcare systems.

The first authorized ATMP medicine in the US came in 2003. In the EU, the first approved product came out six years later, in 2009. The first authorized gene therapy was launched in the EU in 2012.<sup>1</sup>

### ATMPs on the go

As of January 2023 >2,200 active clinical trials of ATMP were on-going globally, and almost 80% of these are for treatments of cancer.<sup>2</sup>

In the present Swedish Drug Discovery and Development Pipeline 2023, there are 65 ATMP projects, of which 45 projects are cell therapies and 20 gene therapies. Most of the projects are in the pre-clinical phase, but we see that 21 of the 65 projects have reached the clinical phase. Of all the ATMP projects, 60% aim at treating different forms of cancers.

### ATMPs as orphan drugs

A high proportion of ATMPs are classified as orphan medicinal products, and the ATMPs that are currently approved mainly target rare diseases. In the EU and the US taken together, 22 unique ATMPs are granted Orphan Drug Designation (ODD), which gives the company regulatory assistance and market exclusivity for a defined time. Of the ODD approved in EU alone the number is even higher, out of 24 approved ATMPs 18 are granted ODD. Out of the 65 ATMP projects in this report there are 13 projects addressing a rare disease, and of these four projects have been granted ODD.

### Market Approval

Market approval is a milestone on the journey towards creating value for the patient. The European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) are responsible for the approval of ATMPs in Europe and the US, respectively.

As a developer of an ATMP, it is important to understand that one is in the field of drug development, an area that is regulated by specific sections of law and that is often based on a structured process. This applies both to the production of the product and to the collection of information proving the benefit-risk profile, in terms of both efficacy and health economic evaluation.

The payment systems for ATMPs differ between countries. Ultimately, it is up to the payer – such as Health Technology Assessment (HTA) authority – to decide which payment model can be considered the most advantageous. Clinical studies need to be designed to align with health technology assessment requirements, including generic quality of life. Given the number of ATMPs under development, health-service planners require that new innovations offer sufficient evidence of the benefit for patients at an acceptable cost.<sup>3</sup>

### Withdrawal of the Market authorization in Europe

Since 1995, when the EMA was created, there have been >1,600 approved medicinal drugs in the EU and of these have around 300 been withdrawn or the market approval (MA) has not been renewed. By comparison, seven of the 24 authorized ATMPs in the EU have been withdrawn from the market by the company itself or they did not renew their MA. Four of the withdrawn ATMPs had been granted ODD. One of the reasons for withdrawal could be due to difficulties in agreeing with payers/HTA on the reimbursements for the companies' therapies. In 2021 a company withdrew the MA only one month after they got the approval. The company said it would close down operations in Europe to focus on the US, due to lack of agreement with European payers.<sup>4</sup>

### The future for ATMPs in Europe

In the recently published Pharmaceutical Strategy for Europe<sup>5</sup>, the European Commission recognises ATMPs as a generational milestone and acknowledges the need for new pricing and reimbursement frameworks that help address the shift from payment over time for chronic treatments to upfront costs for these often one-time therapies.

To address some of the present hurdles, initiatives have been taken to increase the collaboration between industry, the EMA and HTA agencies. Such collaborations aims at harmonizing evidence requirements and facilitate greater acceptance of ATMP. In the future, innovative payment models can help address payers' remaining evidentiary questions while helping to spread the upfront cost of ATMPs, securing timely patient access and alleviating the financial burden for the payers.<sup>6</sup> ■

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5. Shifting the paradigm for ATMPs. <https://efpia.eu/media/636632/atmps-white-paper-cell-and-gene-therapies-related-market-access-issues.pdf>

### FACTS

**Advanced Therapy Medicinal Products** are called ATMP in the European Union (EU) or Cellular & Gene Therapy Products (CGT) in the United States (US). An ATMP could be any of:

- A gene therapy medicinal product containing an active substance, which contains or consists of a recombinant nucleic acid used in or administered to a human being. Its therapeutic, prophylactic, or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence. Vaccines against infectious diseases are excluded.
- A somatic cell therapy medicinal product, which must either be substantially manipulated, or intended for a different essential function in the patient versus the donor.
- A engineered tissue medicinal product, containing cells or tissues that have been modified so they can be used to repair, regenerate or replace human tissue.

A rare disease is any disease that affects a small percentage of the population.

An orphan disease is a rare disease that is so uncommon that there is no market large enough to be financially reasonable for discovering treatments for it. For this reason, governments grant economically advantageous conditions to creating and selling such treatments, called orphan designation. Orphan drugs are such drugs created or sold with orphan designation.

### Incentives to develop ATMPs:

- Developers of ATMPs can obtain reductions in the fees payable to EMA or the FDA for a request for scientific advice or fee reduction for the authorization and post-authorization procedure. There are also additional incentives for small and medium sized enterprises.
- Developers of any orphan product are granted 10 years (7 years in the US) of market exclusivity, including two years' exclusivity for a completed pediatric investigation plan.
- ATMPs/CGTs are biologic medicinal products and upon market approval they are granted 10 years (12 years in the US) market exclusivity.



## ACCESSIBILITY OF NOVEL THERAPIES

# The future of precision medicine

Precision medicine have opened the door to future treatments that recently seemed like fiction. But at a price-per-treatment that's hard for most health systems to bear, how can precision medicine become widely accessible?

There is no limit to human imagination and innovation. We currently witness breakthrough treatments that were fiction just a decade ago. New advancements of cell and gene therapies show a tremendous potential in treating and curing previously terminal or chronic conditions. Modern biotherapeutics – advanced biomolecules administered to patients – are now produced as treatment of large disease areas such as oncology, inflammation, and cardio-vascular diseases. Disease could even be avoided from the start with precise predictive approaches, such as monitoring, life-style adjustments and preventive treatments. But whom is it for?

“Sustainable and equal health requires accessible advanced therapies,” comments Johan Rockberg, professor in directed evolution at KTH – Royal Institute of Technology in Stockholm.

“While we have seen amazing improvement in health benefits from novel advanced therapies, their accessibility has so far been limiting both their regional and global potential –both in terms of patient benefit and missed business opportunity for the industry.”

**“New advancements of cell and gene therapies show a tremendous potential in treating and curing previously terminal or chronic conditions.”**

One such treatment breaks a record – in cost. A new gene therapy to cure haemophilia B, Hemgenix by CSL Behring, costs roughly \$3.5 million per patient and dose, as reported by Nature in December 2022. The beauty of gene therapy is that a single treatment should suffice not only to treat the disease, but to cure the underlying reasons for the disease. Nonetheless, a single expense of \$3.5 million for one patient is a challenge for any cost model.

## Reduced prices ahead

“There are too many examples of ATMPs (advanced therapy medicinal products) that have been approved but later de-registered for business reasons,” says Mathias Svahn, CEO of Nextcell Pharma, a cell therapy company.

He explains that ATMPs are generally relying on autologous use, meaning that the same person is both the donor and recipient. While this greatly improves the chance that the therapy will be accepted by the body, it is very difficult and costly to scale up. Allogenic solutions, where the donor and recipient aren't the same person, could change this.

“As allogeneic solutions are being developed, prices may drop dramatically, while increasing accessibility to patients” Mathias Svahn continues. “Furthermore, ATMPs are usually developed with orphan drug designation, a classification for rare diseases, but can potentially be efficacious for more indications. Thus, when the costs for RnD can be shared between more than one indication, prices and timelines to market can again expect to drop.”

There are more ideas to cut the cost of patient specific therapies by inventive approaches. Johan Rockberg exemplifies a new mindset, called Biosciences 2.0, and a number of technologies that can enable the development of advanced drugs designed for global health systems and markets.

“While costs for patient benefit are justified in health economical models for part of the wealthy population of the planet, the transition of effective treatments into clinics around the world is not likely to happen within the time frames and the scope of the United Nations Sustainable Development Goals by 2030,” Johan Rockberg says.

The enabling technologies exemplified by professor Rockberg span all fields in drug development:

- New modalities that are amendable with platform capability, such as mRNA, gene therapy and of course mAbs (monoclonal antibodies).
- Vaccines and immunostimulatory platforms training T-cells inside patients instead of using ex-vivo cell therapy, such as CAR-T.



- Usage of representative patient material in early assays – to assure that the discovery process delivers drug candidates fit for the world market.
- Many lessons learned from the pandemic for all stages in the process – sharing and caring about the end product throughout the drug development process by all involved.

Both the technologies and the expertise to put them into practice already exist. But is that enough for broadscale implementation of new treatments in healthcare?

## Implementation into healthcare

Sweden is an early adopter of technology, and the same applies for adapting next-generation sequencing for diagnosing patients. For several years, whole-genome sequencing and broad gene panels have been used to tailor treatments to individual patients – precision medicine in action.

In Sweden, these ambitions have been accomplished thanks to a bottom-up initiative from researchers and clinicians in collaboration. A national infrastructure called Genomics Medicine Sweden (GMS) gathers representatives from healthcare, academia, research infrastructures, industry and patient organizations to pave the way for the structural and jurisdictional changes needed.

Today, large-scale genetic analyses provide improved diagnostics within a multitude of areas. One example is pediatric cancer. Children with newly diagnosed pediatric cancer are today offered clinical whole-genome sequencing by GMS together with Barntumörbanken. Out of the first 100 patients, a vast majority showed clinically relevant genetic aberrations with diagnostic, risk-stratifying and predictive impact.

Richard Rosenquist Brandell, professor, clinician and director of GMS emphasizes that different omics technologies will be needed in future healthcare.

“Other technologies studying epigenomics, proteomics or metabolomics will most likely be increasingly important to further improve treatment and outcomes of patients.” Richard Rosenquist Brandell says.

**“Sweden is an early adopter of technology, and the same applies for adapting next generation sequencing for diagnosing patients.”**

A sustainable implementation of precision medicine is challenging in several areas, such as technology, data handling and sharing, follow-up of patients, health economic analyses as well as legal and ethical aspects.

“Many countries have national strategies for the implementation of precision medicine, our Nordic neighbors among others,” says Richard Rosenquist Brandell.

“The national strategies provide a resilience and long-term funding to the initiatives, which otherwise have to attract funding for every step of the way. We need a coordinated national strategy with force as well as long-term financing – to place Sweden in the international front line, but most important, for the benefit of patients,” he concludes. ■



## METHODS

# Methods and definitions

We aim for full transparency regarding methodology. Here we report methods on data collection, processing, definitions and criteria. For questions please contact editor Maja Neiman at [maja.neiman@swedenbio.se](mailto:maja.neiman@swedenbio.se).

## Data collection and inclusion/exclusion criteria

This report aims to describe Swedish companies that are actively developing pharmaceuticals intended for human use. We found 159 companies matching these criteria. The companies were found by updating and complementing the company list from the 2020 pipeline report through communication with incubators, science parks and people within the life science community.

- We define Swedish companies as such that have headquarters in Sweden. Noteworthy is that this excludes AstraZeneca which has a substantial drug development pipeline in Sweden.
- Active in development here means that we exclude companies and projects that are on hold. We exclude companies performing RnD service for others. We also exclude drugs that are completed in the development pipeline, here defined as completed phase III. These completed projects may be in regulatory pathways or launched.
- Within the criteria pharmaceuticals we exclude nicotine substances, probiotics (unless they are registered as drugs) and food supplements. We also exclude platform technologies and companies engaged in drug delivery.
- Human use means that veterinary products are excluded.

Original data to this report was collected in October-December 2022. Therefore, datasets are referred to as Data of 2022

**Company data** was collected through a survey: The Life Science Barometer 2022, open between 22 September 2022 and 11 November 2022. 114 companies responded to the survey. Basic company information from the missing 45 companies (location of headquarter, number of employees, approximate turnover and market) were found on company websites and [allabolag.se](http://allabolag.se).

**Project data** was collected through personal correspondence with the companies during November and December 2022. Projects from last edition of the pipeline report (2020) were updated, and new projects were submitted. Missing data regarding updates and potential new projects were retrieved from the international database Pharmaprojects, as well as from public sources, such as company websites, during December 2022. Sporadic updates on project progress were made in January 2023 (eg approval of Lecanemab).

**Reference data** for international comparisons was collected from Pharmaprojects in December 2022. For comparison with global pharma companies, we selected the top three largest companies (in number of drug assets); Novartis, Roche and Pfizer, complemented with AstraZeneca that has major activity in Sweden. Additional data on regulatory approvals was collected from US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) during December 2022 and January 2023.





Data processing and classifications, company data

All percentages reported are number of a specific response in relation to the number of responses on that survey question. This means that the population size varies between questions. In general, over 100 companies responded to each multiple selection question, and 72 companies to all free text questions. Information of number of employees was collected in headcounts/full time equivalents. These were then transferred to company sizes according to:

- Micro 0-9
- Small 10-49
- Mid 50-249
- Large >250

The yearly turnover of the companies was collected in the categories shown on page 15.

Free text responses were interpreted into categories as follows (for figure on page 17):

- Financing included access to capital, find funding, attract financing, market trends/development, investor risk appetite/trends, availability of risk willing capital, macroeconomic environment, market climate, economical landscape, global financial markets, inflation and similar variants.
- Clinical trials included EU policies concerning clinical trials, access to patients for clinical trials, patient recruitment capacity of hospitals post pandemic etc.
- R&D results included clinical trial results, success of ongoing proof of concept, achievement of key milestones, improvement in drug development etc.

The location of companies on the map (page 20-21) is based on the location of the company headquarters.

Data processing and classifications, pipeline data

The mapping of the Swedish pharmaceutical pipeline is based on projects. We define one project as one therapy (one drug) investigated for one indication. For international comparisons we use the metric of unique drugs to match the format of the database Pharmaprojects.

To enable comparisons over time and between data sources, we use the following project phases:

- Discovery (as defined by the companies themselves, most often meaning projects without a determined candidate drug)
- Preclinical (including Preclinical (CDN))
- Phase I (including Phase 0)
- Phase II (including I/II, IIa, IIb)
- Phase III (including II/III)

After completion of phase III, we define that the candidate is complete in the drug development pipeline. These projects were not included in further statistics but mapped individually in order to see what happened to projects that succeed through the Swedish pipeline.

Modalities were reported by the companies, and translated into the categories highlighted on page 29. We collected data on therapy areas for each indication from the companies, and then we combined them into broader therapeutic areas in order to facilitate comparison over time and to international data sets. We then calculated the relative ranking of therapeutic areas (as highlighted in the figure on page 30) by relating the number of projects within each therapeutic area to the total number of projects mapped that year. Please note that the timeline is irregular. Data was collected yearly between 2006 and 2016, but the data set from 2013 was not applicable for this comparison. After 2016, data was collected 2020 and 2022. The figure is highlighting the top six therapeutic areas from 2022, and traces these therapeutic areas back in time.

We traced progression through the pipeline by calculating the number of projects that changed phase since 2020. The Phase transition success rate, which measures phase progression in a time-independent manner, relates the successful transitions to the total number of transitions (= advancements + suspensions). Please note that suspensions include all reasons for a project to not be included herein (failed, on hold, project sold to an international company or discontinued for other reasons). Highlights, as reported on page 37, were subjectively chosen by the authors and the editor of the report.

Therapeutic Area (as shown in Project and Company List):	Including (Categories reported by the companies):
Oncology	Cancer, oncology, immuno-oncology
Neurology/CNS (central nervous system)	Neurology, psychiatry, pain, sleeping disorders, sensory
Immunology	Autoimmunity, immunology, immune system, inflammation, transplantation, rheumatology
Infection	Bacterial infection, viral infection, parasites, AIDS/HIV
Endocrinology/Metabolism	Endocrinology, metabolism, diabetes, alimentary/metabolic
Cardiovascular	Cardiovascular, heart diseases
Dermatology	Dermatology, skin, wound healing
Gastrointestinal	Gastrointestinal, digestive disorders
Haematology	Haematology, blood disorders
Nephrology, urology	Nephrology, urology
Obstetrics, gynecology	Obstetrics, gynecology
Respiratory	Respiratory, pulmonary
Other	Hepathology, otolaryngology, ophtalmology, trauma, musculoskeletal, osteoporosis, rare diseases, other indications

**DISCLAIMER**  
The content of this report is based on information gathered in good faith and is believed to be correct at the time of publication.





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