

# The Swedish Drug Discovery and Development Pipeline 2020



## 420 Projects

420 R&D projects, from discovery to Phase III. Most projects are within Oncology, Neurology, Endocrinology/ Metabolism and Infection.



## 148 Companies

148 Swedish R&D pharma and biotech companies are actively developing new drugs. 53% of the companies have projects in clinical phase I-III.



## Highlights

Special focus on Drug delivery, Cell- & Gene therapy and Rare diseases.

**sweden BIO**  
The Swedish Life Science Industry Organization



**Invest Stockholm**

**invest in skåne**  
part of business region skåne

# Thank you!

We would like to express our special thanks to everyone who helped and contributed to making this report a reality, without whose contribution it would not have been possible to assemble the companies and content presented in the report. Thanks are due to, by no means exclusively, to all the science parks, incubators, other supporting organizations and individuals who shared their valuable knowledge and insights and spread information of the project and survey.

This report is done in cooperation between and with financial support from Business Sweden, Business Region Göteborg, Invest in Skåne, Invest Stockholm and Vinnova – Sweden's innovation agency.

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## Share the knowledge

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The content of this report is based on information gathered in good faith and is believed to be correct at the time of publication. SwedenBIO can however provide no guarantee regarding the accuracy of this content or any misprints that may occur.

# Bigger, broader and with a willingness to expand

*Sweden maintains its strong position in drug discovery and development, from early discovery to phase III trials, and parades project portfolios with distinct commercial values*

This report highlights the state of the Swedish pharmaceutical drug R&D pipeline and provides insights into such topics as the therapeutic areas being explored, the distribution of research projects in clinical phases, the number of potential first-in-class medicines, and some of the new areas of scientific opportunity being applied to advanced treatments. The focus is primarily on potential new medicines in research stages in discovery, preclinical or clinical development as of spring 2020. We estimate that this report covers the vast majority of active companies and projects in Sweden. However, the number of ongoing discovery and preclinical projects in Sweden have possibly been underestimated.

This year, 148 Swedish companies falling into this category were identified, of which 79 have projects in clinical development, phase I-III. The data presented includes in-depth analyses of the clinical stage projects and an overview of discovery and preclinical projects. Background information on these companies is also presented including statistics on size, geographical location and number of employees. Most of these companies are small- or micro sized enterprises.

There is a strong link between the companies and universities/academia, with the majority being spinouts from universities, and many having on-going academic collaborations, both national and international. The breadth of the ongoing research is also impressive, both in terms of number of indications in different therapy areas, and in the number of different types of compounds.

## THE SWEDISH DRUG PIPELINE CONTINUES TO GROW

SwedenBIO has followed the development of the Swedish drug pipeline since 2006. Our latest report was published in 2016.

*“The high proportion of projects that have the potential to be first-in-class reflects exciting scientific opportunities and innovative approaches being used by researchers to address critical unmet patient needs.”*

This year's edition includes an exclusive list of all discovery, preclinical and clinical projects, covering the different compounds, indications and progression of in total 420 projects – an increase by 51 projects compared to the previous report in 2016. There are currently 148 projects in clinical development. An accumulation of projects in phase II is clearly visible, but there is also an increase in the numbers of projects in preclinical and phase 0 stages, marking a 51% increase as compared to 2016.

## FOCUS ON NEW TECHNOLOGIES

In this year's report we highlight Drug Delivery and Cell- and Gene Therapy, only two areas of many where Swedish companies are in the frontline. Sweden has a long tradition in developing drug delivery but also deep-seated experience in the new and exciting fields of cell- and gene therapy. The selected highlighted areas are two which the Swedish government has elected to support and advance by allocating money both through relevant funding agencies, and through investment in the national research infrastructures.

Further, we are highlighting rare diseases, as many as 25% of the entire pipeline is addressing treatments in this area, a continued attractive field for Swedish companies.

## Our report covers the following topics:

- Orientation in the innovation landscape and an overview of the companies
- A map of the research areas the 148 companies are involved in
- Presentation of the findings including therapy areas, type of compounds, development stages, and numbers
- Hot spots in Sweden
- A list of companies and their 420 projects as an appendix

Wishing you an enjoyable and informative read!



Project Leader  
Susanne Baltzer, PhD



Editor  
Sara Gunnerås, PhD

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### → Appendix - Project List

List of all 420 projects  
+ list of rare disease projects

SWEDENBIO

# The Swedish life science sector is a power engine of innovation

Once again, the Swedish drug discovery and development pipeline has been outlined and, once again, it proves our remarkable strength. Since the last report was produced in 2016, the pipeline has grown broader with more projects and companies and has also matured significantly. Combined, this shows a promising future for the Swedish drug developing companies.

At SwedenBIO, the Swedish Life Science Industry Organisation, we find it particularly encouraging to see how the companies are liaising internationally. This is of utmost importance in order for the innovations spurring from our dynamic ecosystem to turn into growing, successful companies.

I am pleased to conclude that nearly every company in this report has strong business ties to the international life science community. Not only do we have an impressive research pipeline, but we also have broad connections to international experts and business networks who vouch for our readiness to enter the global market.

The courtship is mutual; close to half of the projects have already attained international funding and the associated business contacts are prevailing. Since the foundation's inception, this is precisely what SwedenBIO has been working for: to build a solid, local Swedish life science community with business-to-business contacts between companies of all sizes and levels of maturity, while connecting to the global best-of-the-best within science, financing, regulatory etc. We are convinced that this is the road to success.

This is why we do this report, to see what is currently happening, to make it easily accessible to connect with us, and to see where we are heading.

This is also why we have created Nordic Life Science days, the largest life science partnering meeting in the Nordics, which annually gathers some 1400 delegates from 40+ countries to liaise with one another in over 3000 face-to-face partnering meetings, flanked with a crisp program to show the latest from the frontlines of innovation.

## ABOUT SWEDENBIO

SwedenBIO is the national association for the life science industry in Sweden. Our 260+ members are companies active within pharmaceuticals, biotech, diagnostics and medtech, including companies ranging from small start-ups and SMEs right through to the larger enterprises. Many are engaged in research, development, clinical trials and production. Others are experts in specific associated fields such as IP, law, finance, product development, life science communication, recruitment and business development. SwedenBIO is member-driven, and our mission is to promote an environment bringing success and growth to the entire Swedish life science industry.

→ Find your next business partner at [www.swedenbio.se](http://www.swedenbio.se)



Together with our Nordic neighboring countries, Sweden forms an epicenter of a power engine, an engine that is generating innovations that are spreading across the world to improve patients' lives everywhere. We have a longstanding tradition within life sciences, both in the academic and industry environments, and, most importantly, in the highly creative intersection between the two.

On behalf of the Swedish life science industry, we welcome you to take part of this dynamic environment – to join us with collaborations, investments and partnerships.

We look forward to connecting!

Helena Strigård, Director General SwedenBIO

→ Visit us at [www.swedenbio.se](http://www.swedenbio.se) / [www.nlsdays.com](http://www.nlsdays.com)

## NORDIC LIFE SCIENCE PARTNERING AT ITS BEST

Nordic Life Science Days is the largest Nordic partnering conference for the global Life Science industry. Bringing together the best talents in Life Science, offering amazing networking and partnering opportunities, providing inputs and content on the most recent trends. Nordic Life Science Days attracts leading decision makers from the Life Science sector, not only from biotech, pharma and health-tech but also from finances, research, policy and regulatory authorities. Based on cutting-edge and advanced partnering and networking tools, Nordic Life Science Days showcases the best the Nordic region has to offer.

→ Read more at [www.nlsdays.com](http://www.nlsdays.com)

THE OFFICE FOR LIFE SCIENCES

# A longstanding governmental commitment to life sciences

The life sciences have been a priority area for Swedish governments for decades, as illustrated by the substantial investments made in research, research infrastructure and programmes to stimulate innovation in Sweden's highly dynamic intersection between academia and industry.

The government has four innovation partnership programmes, one of which has life sciences as its main focus. In 2018, an Office for Life Sciences was established within the government offices, bringing together expertise from the ministries of Health and Social Affairs, Education and Research as well as Enterprise and Innovation, all representing policy areas that are central to the development of effective strategies in this complex field. The corona pandemic has highlighted the urgent need for strengthened collaboration and co-creation within the sector.

## LIFE SCIENCES STRATEGY LAUNCHED 2019

With a national life sciences strategy adopted by the end of 2019, stakeholders from healthcare, academia and industry are now working together to deliver on the priorities and goals set out.

The overarching aim is:

*“Sweden aims to be a leading life sciences nation. Life sciences contribute to improving health and quality of life of the population, ensuring economic prosperity, advancing the country as a leading knowledge nation and achieving the 2030 Agenda for Sustainable Development.”*

Close cross-sectorial cooperation is widely regarded as a Swedish strength and provides a competitive advantage often reiterated by investors and business leaders when making decisions on where to engage. The collaborative spirit between academia, healthcare and industry has helped us overcome many challenges in the past.

## LOOKING INTO THE FUTURE WITH CONFIDENCE

Through intense work and the involvement of many stakeholders, a strategy with both long-term and short-term goals has been developed. It sets the ambition high in making clever use of Swedish areas of strength, such as our unique access to health data and biobanks, our world class research infrastructures, high quality clinical trials and advanced position in implementing precision medicine and AI in modern healthcare. This puts the government and the government agencies – along with the sector as such – in a good position to make sustainable decisions that will help make Sweden an even stronger life sciences nation. We have the means to look into the future with confidence. As is shown in this report, the drug discovery and development pipeline continues to deliver impact, and it is the government's ambition to keep putting initiatives and policies in place to help support this pipeline to grow and mature.

A strong life sciences sector is, and will continue to be, at the heart of Sweden's response to global health challenges.



*“A strong life sciences sector is, and will continue to be, at the heart of Sweden's response to global health challenges”*

Jenni Nordborg  
National Life Science Coordinator,  
Special Advisor to the Government,  
and Head of the Office for Life Sciences

## FACTS ABOUT

The Office for Life Sciences has been created to serve as a link between life sciences sector stakeholders and the work of the Government. The Office aims to promote knowledge development, innovation and quality – in health and social care and at universities and higher education institutions – and improve conditions for the establishment and operation of life sciences companies in Sweden.

VINNOVA

# Systems innovation in life science

Sweden is a small country which nevertheless makes a major contribution to the international life science arena. Sweden continuously ranks as one of the most innovative countries in the world and hosts a vibrant community of large and small life science companies ranging from global pharmaceutical companies to biotech, medtech, healthtech and service providers. As Sweden's innovation agency, Vinnova is charged with empowering this ecosystem, boosting innovation capacity, and contributing to sustainable growth, based on the global goals laid out in the 2030 Agenda for Sustainable Development.

## 300 MEUR TO RESEARCH AND INNOVATION

Vinnova provides roughly 300 MEUR of funding annually to research and innovation, stimulating intersectorial and interdisciplinary collaborative milieus and programmes where knowledge and skills meet and co-create from different perspectives. Our support provides opportunity to experiment and test new ideas before they become profitable through centres for industrial research, systems demonstrators, and testbeds. We work with companies, other governmental agencies, politicians, and international organizations to keep Sweden at the cutting edge of life science.

## ADDRESSING THE CHALLENGES OF TODAY AND TOMORROW

The life science sector is firmly placed at the centre of a digital and technological revolution, characterized by the increasing dependency on access to deep data and Real World Evidence (RWE) that requires new forms of collaboration between organizations and disciplines. Approaches such as precision medicine and advanced therapeutics result in an increased reliance on digitalization, research infrastructure and novel business models all of which create new opportunities for innovation and growth. At the same time, an increased awareness of the interdependency of physical and mental health is developing through the use of novel approaches to disease prevention, wider access to sustainable sources of food and a healthy community and environment, all encouraging missions-based approaches to addressing tomorrow's grand challenges in health and healthcare.

## SUPPORT AND CONNECT

Vinnova supports this evolution of the Swedish life science ecosystem by funding start-ups and scale-ups, triple helix collaborations, innovation hubs and incubators, as well as connecting Swedish businesses to the European and international community of innovation funding and research efforts.

→ Visit us at [www.vinnova.se](http://www.vinnova.se)

## Vinnova supports the Swedish life science ecosystem



Nordic Life Science Days, the largest Nordic partnering meeting connecting businesses to the world.

BUSINESS SWEDEN

# A gateway to business opportunities in Sweden

*Business Sweden, together with the regional investment promotion agencies, has extensive knowledge of the Swedish life sciences landscape and can help international companies and investors find the best opportunities Sweden has to offer.*

The life sciences sector is of high strategic importance in Sweden and a setting of R&D excellence and world-class innovation. This is evidenced by a strong growth in Sweden over the past 15 years of university spinouts and start-ups with a life sciences focus, in particular with regard to companies developing novel therapeutics, as well as an increase in international strategic alliances mainly through external innovation channels with Big Pharma. Life science is Sweden's second largest export industry, with pharmaceuticals having an export value of 10 billion Euro (2019), making this sector a strategic priority for the Swedish government. Backed by a strong tradition in life sciences, particularly in pharmaceutical R&D, Sweden wants to stay at the forefront of advances in this sector.

This report produced by SwedenBIO provides valuable insight into and information about individual products in development. Not only does it showcase the strength, focus and attractiveness of the Swedish drug discovery and development pipeline for collaboration and investments, but is also an important tool for the ongoing monitoring of the state of the industry.

## BUSINESS SWEDEN

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. We help international companies expand their business in Sweden through entering into strategic partnerships or investing in Swedish companies. Business Sweden is present in 50 of the world's most promising markets and owned by the Swedish Government and commercial sector, a partnership that provides access to contacts and networks at all levels.

Business Sweden's advisors within life sciences are bringing the best opportunities from Sweden to leading pharmaceutical companies and investors in the US, Japan, South Korea, as well as Europe.

## REGIONAL INVESTMENT PROMOTION AGENCIES

Business Sweden has a close collaboration with several regional investment promotion agencies in Sweden, including Invest Stockholm, Business Region Göteborg, and Invest in Skåne.

The regional investment promotion agencies can advise about the following activities:

- **Support in finding investment opportunities:** Joint ventures, Acquisitions, Venture Cap, Co-operation. Assistance in Business Development discussions based on sector specific information and long experience
- **Establishment service:** Introductions to relevant contacts among authorities, utility providers and professional service companies such as lawyers, accountants, relocation specialists and recruitment companies. Practical assistance in finding facilities, land and other essentials for getting established in the region



Representatives of the Nordic Life Science Consortium at BIO International Convention 2019.



*“The Life Science sector is of high strategic importance in Sweden and a scene of R&D excellence and world-class innovation”*

**WANT TO KNOW MORE?**

**BUSINESS SWEDEN**

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# An ecosystem to watch and engage

*With a leading-edge business community across drug discovery and development and cultivated ties to academia and health care systems.*

Sweden hosts a diversity of micro- to medium-sized companies, emerging companies, as well as an array of expanding and maturing counterparts. Comfortably nested amongst a national sea of incubators, hubs, parks and meeting-points for companies, academia and health care. Sweden's ecosystem for drug discovery and development is flourishing.

Sweden has a tradition of strong investment in research and development (R&D): spending 3.4% of gross domestic product on science (European innovation scoreboard 2019).

One unique aspect of the academic research in Sweden is the long-standing law known as professor's privilege: i.e. university employees keep the intellectual-property rights to discoveries they make. This encourage the creation of spinout companies, increases patenting activity and helps universities to recruit high-quality researchers.

## 148 COMPANIES DEVELOPING NEW MEDICINES

In this report we present data on 148 companies. The companies included are those headquartered in Sweden and with R&D in drugs for human use. The vast majority are small and mid-sized enterprises (SMEs), and a handful also have their own sales of pharmaceuticals.

**3.4%**  
R&D/GDP

## SMES DOMINATE THE LANDSCAPE

All but one are small and mid-sized enterprises, SMEs (0-249 employees) and about a handful companies have their own sales of pharmaceuticals. Small and micro-sized enterprises (0-49 employees) dominate the business landscape, accounting for 95% of all firms.

We see a positive trend in the size of the companies, as we find more companies with 10 or more employees compared to previous report, in total 29. Comparing the numbers of employees from the previous report and the most recent public data (data from Dec. 2015 vs. data from Dec. 2018) the number of micro sized companies (0-9 employees) have decreased from 87% to 80%.

The segment of mid-sized companies (50-249 employees) includes a number of established companies with both R&D, products and/or platform technologies on the market. By the end of 2019, according to the survey, this segment consisted of the following companies;

- Affibody, Stockholm
- Alligator Bioscience, Lund
- Bioinvent, Lund
- Camurus, Lund
- Oasmia Pharmaceuticals, Uppsala
- Orexo, Uppsala

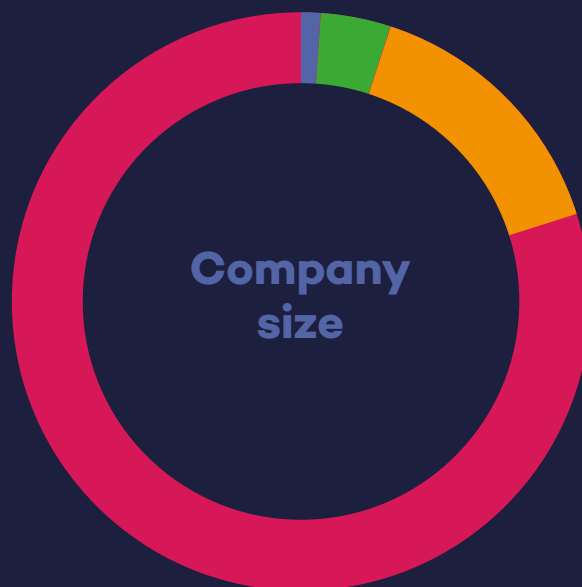
There is one large international biopharmaceutical company with headquarters in Sweden: Sobi. Sobi is focused on the development and commercialization of late-stage projects in rare hematological and immunological conditions.

**1%**  
LARGE

**4%**  
MID

**15%**  
SMALL

**80%**  
MICRO



**7-8/year**  
New companies

**EMERGING COMPANIES**

Sweden is known for its active start-up ecosystem. Based on those included in this drug development pipeline, there have been on average 7,4 new companies founded annually since 2010.

**THE VIRTUAL TREND – SMART RESOURCE & KNOWLEDGE SHARING**

In this industry, many companies stay small/virtual, meaning that they have few in-house employees and a significant part of their business allocated to external consultants and specialized service providers e.g., R&D, clinical trials, regulatory, finance and accounting.

In Sweden, there exists a wide breadth of experts and virtual companies that collaborate to share expertise, thus being resource-efficient.

**EXTERNAL CONSULTANTS**

**57%**  
Consultants / Employees

**71%**  
Of consultants in R&D

**4/5**  
Plan to recruit

**EXPANSIVE COMPANIES**

When asked about development aims in 2020–21, as many as 80% of companies stated plans to hire more employees and/or consultants, with 47% planning to hire both employees and consultants.

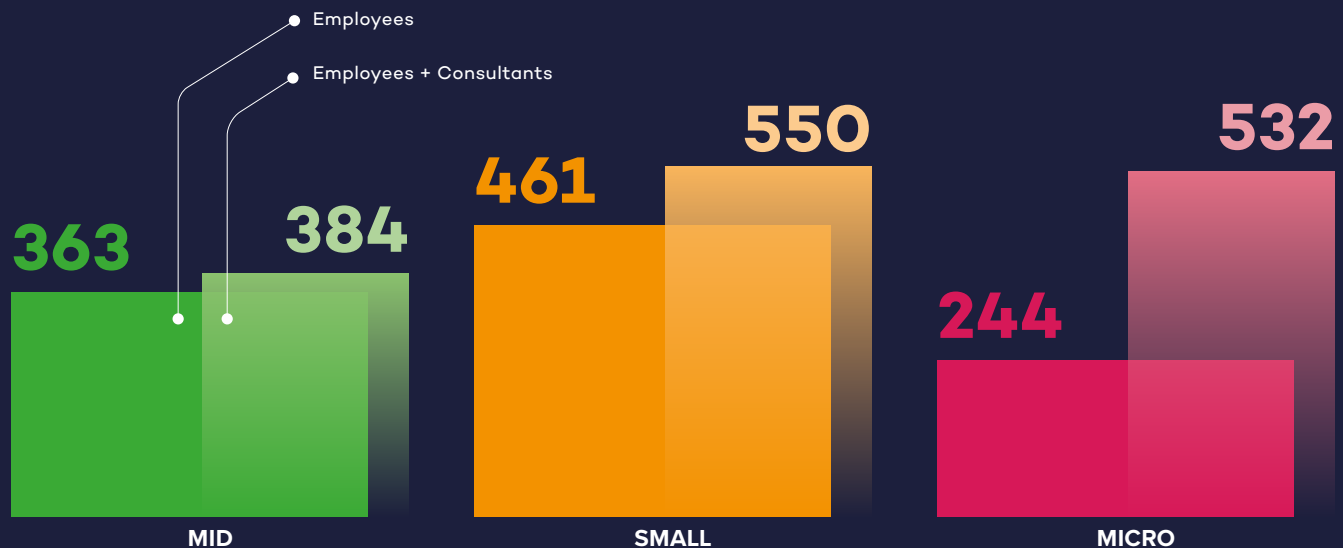
**EXPANSION PLANS 2020-2021**

 **46%**  
More employees and consultants

 **80%**  
More employees or consultants  
96 SME's on their expectations for development during 2020-2021 regarding R&D-activities.

**Employees and consultants in SME's**

Number of employees and consultants in Full Time Equivalent .



# Sweden's thriving undergrowth

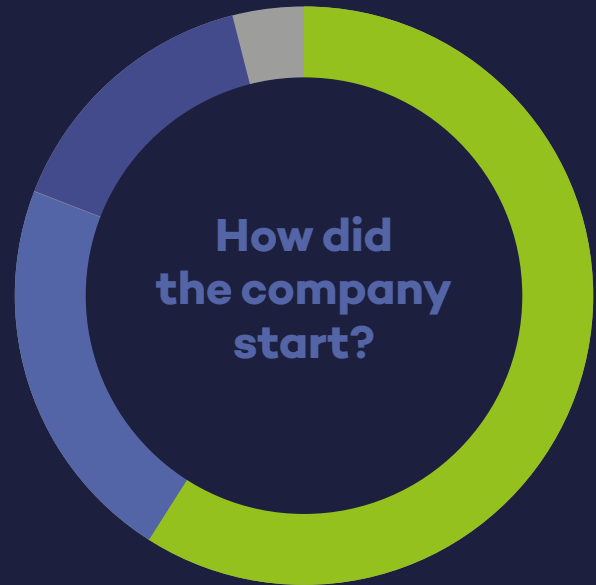
*Academia and health care foster a stable majority of Sweden's earliest ideas translating to industry developments*

## CLOSE RELATIONS

Of the 148 companies two out of three are spinouts from universities and/or hospitals, with three quarters of new ideas originating from:

- Lund University
- Karolinska Institutet
- Uppsala University
- Sahlgrenska Academy
- Umeå University

The remaining group of companies surveyed are either independently started or a spin-off from another company.



**59%**  
Spinout from  
academia/  
hospital

**22%**  
Independent

**15%**  
Spin-off from  
company

**4%**  
Other/  
Undisclosed

## INTERVIEW



Klementina Österberg, CEO  
GU Ventures

## A BOOMING PIPELINE OUT WEST

### THE DRUG DISCOVERY AND DEVELOPMENT PIPELINE IS REALLY BOOMING IN GOTHENBURG, TELL US WHY!

“Yes, it is amazing. We have two great universities, a world renowned research hospital, strong industry players, many small innovative companies and a well-developed support system – all creating the ideal environment for ideas and young companies to flourish. It’s all about “paying it forward” on all sides and about coordinating efforts that creates higher quality and better results in the end.”

### WHAT IS GU VENTURE'S ROLE IN ALL OF THIS?

“GU Ventures is recognised as one of the world’s top incubators, thanks to our well-proven track record in finding disruptive ideas and turning them into successful businesses through strong teams and close relationships with investors, clients, partners and suppliers. There are many moving parts that need to work together - we are the oil that keeps them moving smoothly.”

### AND HOW DO YOU ACHIEVE A GOOD MATCH?

“You have to put yourself out there. You have to go fishing in the international pond with the right bait. You have to be persistent and eventually you might catch a prize fish!”

→ Want to know more? [www.guventures.com](http://www.guventures.com)

About three out of five companies state that they are part of a community, i.e. a Science Park and/or an incubator. The most popular communities the companies mention are listed on page, 14–15.

**3/5**  
are part of a  
community



**60%**  
of the companies  
are members of the  
life science industry  
organization  
SwedenBIO

## INTERVIEW



David Beijker, CEO  
Affibody

### AMBITIONS AS A LEADER IN BIOTHERAPEUTICS

Affibody is a Swedish life science-company which has grown rapidly in recent years, from 28 employees in 2016 to 60 in 2020.

#### HAS IT ALWAYS BEEN A STRATEGY OF YOURS?

“We have a long term ambition of becoming a leading in player within biotherapeutics. We are building our company and an extensive pipeline on the strengths of our unique, proprietary platforms that can generate highly potent and selective protein drugs with differentiated biodistribution. Our intent is to build an integrated biotech company with development, manufacturing, and commercialization expertise.”

“With this intent and on the back of strong clinical data, including up to two years efficacy and safety, emerging from our Phase 2 ABY-035 (IL-17) program we are now preparing for late stage development. At the same time, we have a large number of preclinical candidates that may enter clinical trials within the coming years and, therefore, need to make sure we have adequate resources to manage these candidates.”

#### WILL YOU CONTINUE TO AIM AS HIGH IN TERMS OF EXPANSION?

“We will continue to work with the same type of attitude as we have had before which means we are looking to build a company with the resources and competences to be able to ensure long-term success. At the stage we are now, we do project a less aggressive growth in terms of employees, yet more aggressive in terms of new projects and collaborations.”

→ Want to know more? [www.affibody.se](http://www.affibody.se)



# 4 hot spots in Sweden

– for drug discovery and development and the foremost universities and organizations for financing, business and innovation support.

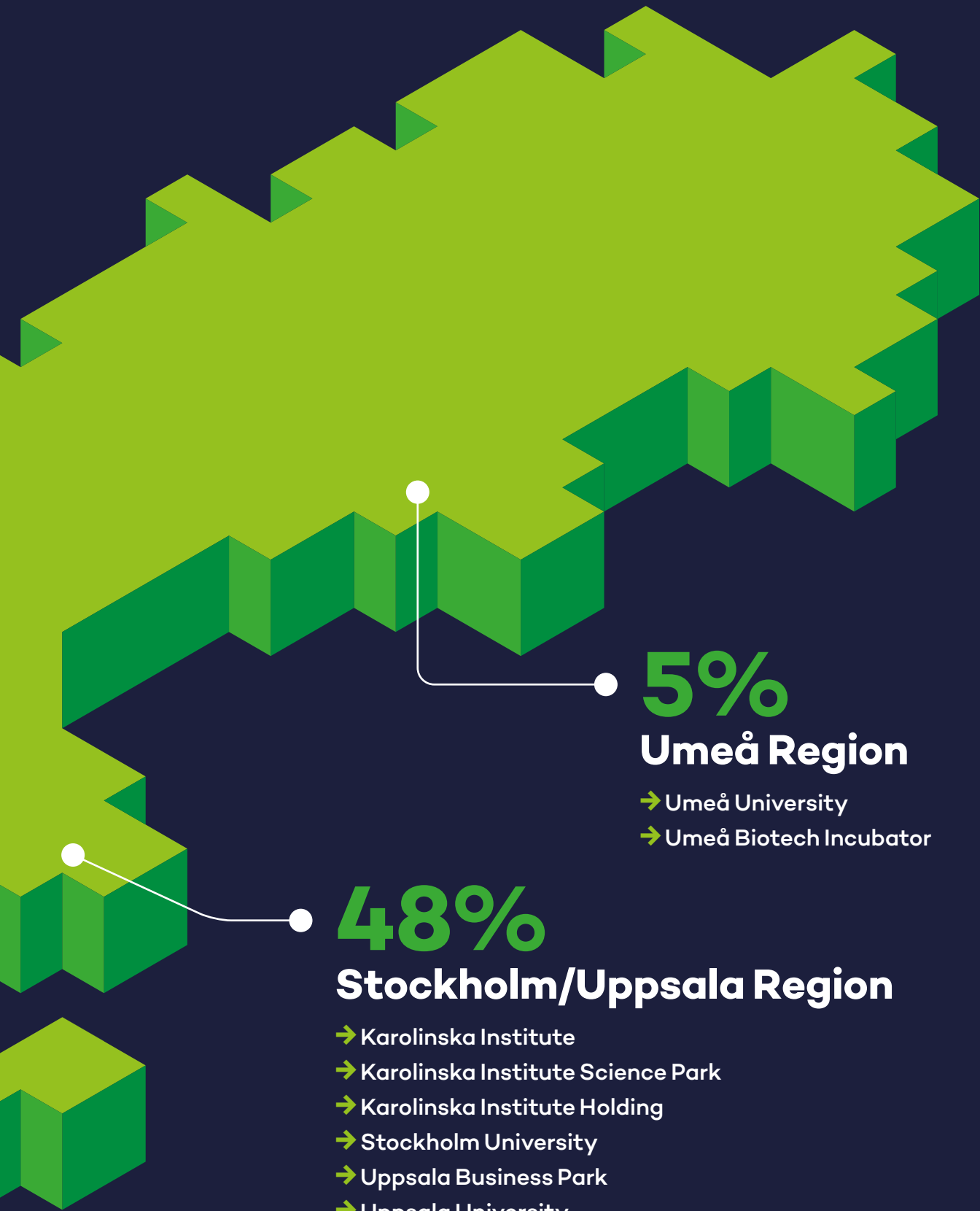
## 17% Gothenburg Region

- AZ Bioventure Hub
- GU Venture
- Sahlgrenska Academy
- Sahlgrenska Science Park

## 30% Malmö/Lund Region

- Lund University
- Lund University Holding
- Lund University Innovation
- Medeon Science Park
- Medicon Village
- SMILE Incubator





**5%**  
**Umeå Region**

- Umeå University
- Umeå Biotech Incubator

**48%**  
**Stockholm/Uppsala Region**

- Karolinska Institute
- Karolinska Institute Science Park
- Karolinska Institute Holding
- Stockholm University
- Uppsala Business Park
- Uppsala University
- Uppsala University Holding

INTERVIEW



Jennie Ekbeck, CEO  
Umeå Biotech Incubator

**WHAT IS THE KEY TO SUCCESS IN HOW UBI SUPPORTS ITS COMPANIES?**

“At Umeå Biotech Incubator, everything starts with the global market. The first thing that happens when a new start-up joins in is to form that global strategy – to understand that which clients and investors are seeking.”

**WHY IS IT IMPORTANT TO THINK INTERNATIONAL FROM DAY 1?**

“Because that is how you do it right from the beginning, by starting with the end. And that means understanding that competition is global, as is the market for your product or service. Building such relationships early-on will help bring in some high-quality investors and business collaborations later on.”

**INTERNATIONAL CONNECTIONS COME VERY NATURALLY TO LIFE SCIENCE COMPANIES IN UMEÅ – WHY IS THAT?**

“We are used to overcoming physical distances to collaborators, wherever they are, be it in Stockholm or the US. Thus, the competence building our companies comes from all over and has contributed to bringing solid investments here.”

→ Want to know more? [www.ubi.se](http://www.ubi.se)

# Born global

*Academia and health care foster a stable majority of Sweden’s earliest ideas translating to industry developments*

**INTERNATIONALLY CONNECTED**

Sweden actively contributes to the global drug-discovery and development ecosystem by being well-connected internationally, thus ensuring a constant flow of creative ideas, valuable skills and experiences, as well as the necessary capital to fund the operations.

Companies included in this report were asked how global they are and what kind of international contacts and collaborations they have. From the survey, we find that 45% of the companies had different kinds of international connections.

**DAILY OPERATIONS**

Some of the connections have direct impact on the company’s daily operations. International board members often contribute with valuable experience, know-how and insights that cannot be sourced in Sweden. Research collaborations, with foreign universities and companies are very common and a most valuable way for the companies to gain competitive knowledge. The staff often consists of international experts and recruits.

Half of the companies have attracted international investors contributing with “intelligent capital” to the benefit of the companies and companies also mention international members of their scientific advisory board as a valuable source of business/research knowledge.

**BUSINESS CONNECTIONS**

Other kinds of international connections are more of an operations nature, with vast majority of the companies buying R&D-related services abroad such as CRO-services, but also include business-related international connections, i.e. international license (incl. in- or out licensing) and/or distribution agreements.



**How global is your company?**

108 SMEs responses about their different types of international cooperation.





**100%**  
of the respondents have  
one or more international  
connections out of the  
categories below

**INTERVIEW**



Jessica Martinsson, CEO  
Sprint Bioscience

**OUTLICENSING AS A PATH TO THE GLOBAL MARKET**

Recently, Sprint Bioscience successfully out-licensed two projects – one to Petra Pharma in New York and one to LG Chem in South Korea.

“We believe that the success of effectively managing projects lies in the close collaboration and interaction between the various disciplines involved in the work. Our market is worldwide and we build our network globally, both in the scientific sector by connecting with key opinion leaders in the field, and also in the business sector by forging strong relationships and beneficial affiliations,” says Jessica Martinsson CEO, Sprint Bioscience.

Sprint Bioscience is focused on preclinical research within oncology. The company identifies, launches, and runs drug development projects and out-licenses them in the preclinical phase to the global pharmaceutical industry.

→ Want to know more? [www.sprintbioscience.com](http://www.sprintbioscience.com)

**50%**

We have  
international  
investors

**40%**

We have  
ongoing clinical  
trials abroad

**35%**

We have license  
agreements  
with foreign  
companies

**16%**

We have distribu-  
tion agreements  
with foreign  
companies

**37%**

Other kind of  
international  
connection

# Financial landscape

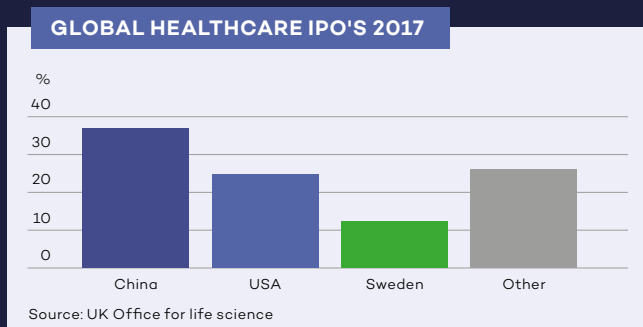
*Sweden stands out in the crowd, in both the private & public financial arena.*

Over the past decade, there has been a steady increase in the means by which Swedish life science has been able to fund operations. The most common source of funding is made up of private equity investors, but both the stock market and soft funding have increased. In a sector with substantial capital requirements, it is reassuring to see companies becoming less reliant on one single category of investors.

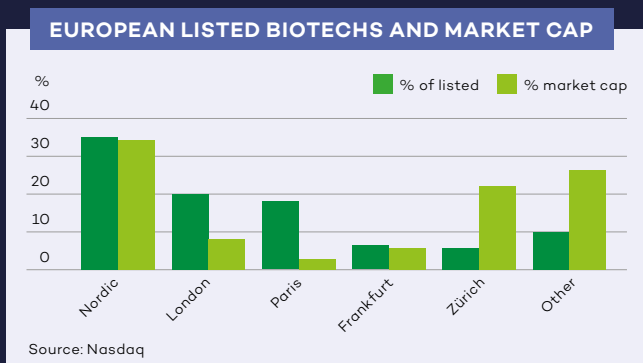
## THE BEATING HEART OF HEALTHCARE IPO'S

Over the last decade, the Nordic countries, – Sweden in particular – have developed into a global hub for healthcare IPOs. Close to 220 healthcare companies are listed on Nasdaq Nordic's main list and the Multilateral Trading Facilities First North Growth Market and Spotlight, constituting a significant proportion of the stock markets.

In 2017, 13% of global healthcare IPOs took place in Stockholm, making Sweden the third most active country after China and the United States.



Looking at the European biotech sector, 212 companies were listed in January 2020. Nasdaq Nordic's main list and First North Growth Market host 35% of these companies, with 34% of a total market cap of 148 Bn EUR, making the Nordic countries a major life science powerhouse.



With Sweden as the dominating Nordic country in life sciences, the number of IPOs are unique from an international perspective, giving early investors exit opportunities and companies an exceptional opportunity to gain international exposure, as well as grow and develop projects. The strength of this ecosystem promotes the successful development of innovative products that are well-prepared for a global market.

## 43% OF THE PIPELINE COMPANIES LISTED

Among the 148 drug discovery and development companies in this survey, we find that more than two out of five are listed on a market place.



**57%**  
Private

**15%**  
Nasdaq Nordic's  
Main List

**15%**  
Spotlight Stock  
Market

**13%**  
First North Growth  
Market

### CATCHING THE EYES OF INVESTORS

With half of the companies already having attracted international venture capital, Sweden's drug discovery and development pipeline is gaining increased attention from abroad.

International investors not only contribute with capital, but also with essential competence, experience and international networks, referred to as "Intelligent Capital" in Sweden.

### SOFT FUNDING REQUIRES HIGH-QUALITY R&D

Over the last decade, soft funding from national programs has almost tripled, as the source used for funding of Swedish life science companies, while EU-program funding doubled, as measured by their share of all financing activities. This type of funding is sought-after in tough competition between sectors and countries, often with multiple rounds of screening each project's research quality and commercial potential. Thus, the success in attaining soft funding by small Swedish life science companies is an indicator of industry strength.

(Source: Bridging the Gap, SwedenBIO 2019)

**50%**  
We have  
international  
investors

#### INTERVIEW



Mats Persson, CEO  
Hamlet Pharma

### ATTRACTING SOFT FINANCING – HIGH-SCORED ON EU GRANT

Hamlet EIC Accelerator grant application not only received highest marks, but was also approved in full, to the amount of €2.2M. "The fact that the EU chooses to invest in our project is a very important quality stamp", says CEO Mats Persson.

"It's a new mechanism of action, based on solid research from Lund University. Therapeutic efficacy has recently been demonstrated in patients with bladder cancer".

Hamlet kills cancer cells of different origins (more than 40 different types of cancer cells) and is active in multiple oncology and dermatology indications.

"It's a fascinating molecule originally derived from breast milk with strong biological effects. For clinical trials, we have developed a second generation synthetic drug candidate Alpha1H".

→ Want to know more? [www.hamletpharma.com](http://www.hamletpharma.com)

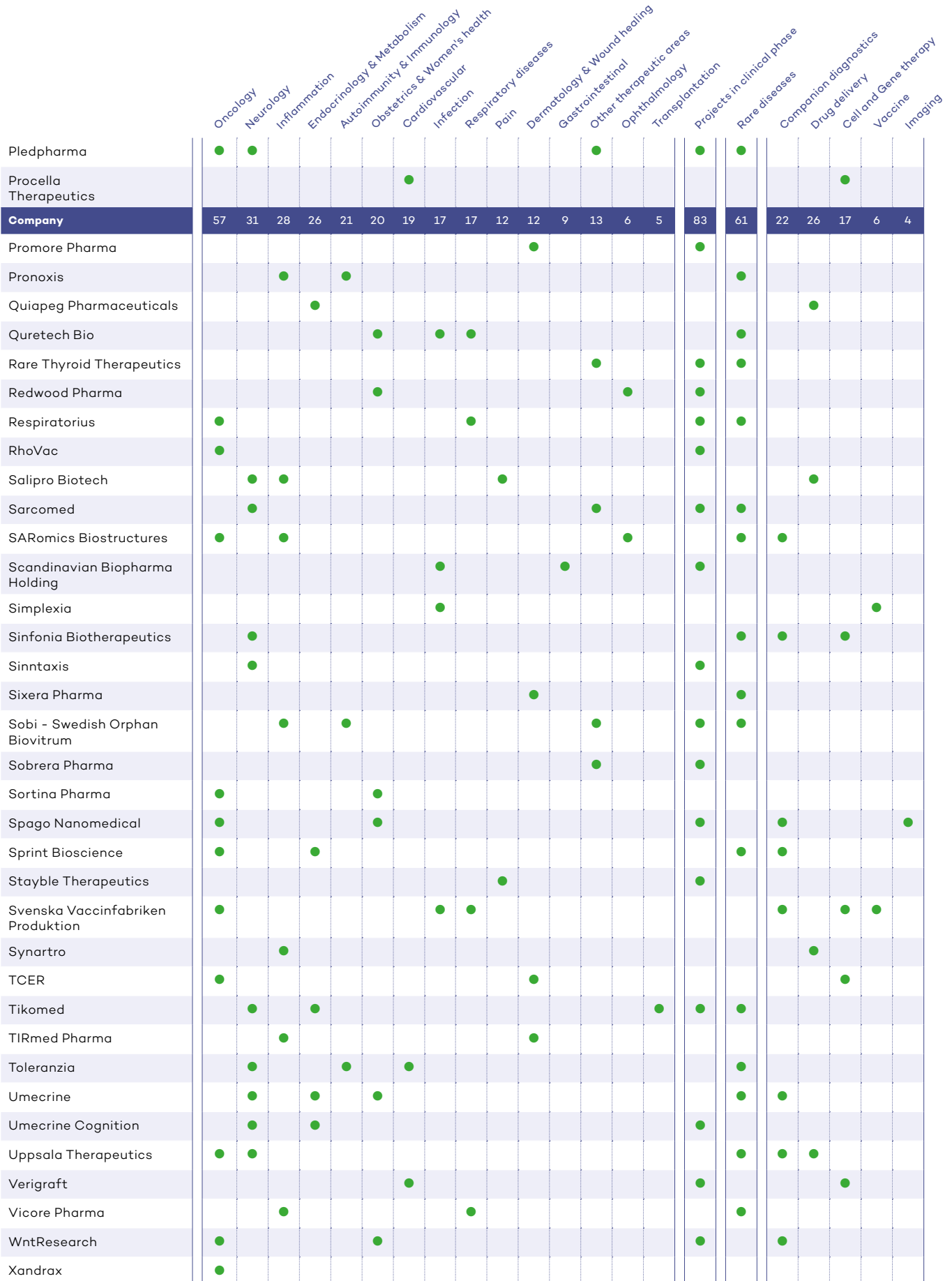
# Companies A-Z

Company	Therapeutic Areas															83	61	22	26	17	6	4
	57	31	28	26	21	20	19	17	17	12	12	9	13	6	5							
	Oncology	Neurology	Inflammation	Endocrinology & Metabolism	Autoimmunity & Immunology	Obstetrics & Women's health	Cardiovascular	Infection	Respiratory diseases	Pain	Dermatology & Wound healing	Gastrointestinal	Other therapeutic areas	Ophthalmology	Transplantation	Projects in clinical phase	Rare diseases	Companion diagnostics	Drug delivery	Cell and Gene therapy	Vaccine	Imaging
2A pharma	●	●			●	●		●	●							●					●	
Abarceo				●																		
Abera Bioscience	●					●		●	●												●	
Active Biotech	●		●									●		●		●	●					
Acucort	●		●		●				●				●						●			
Affibody	●				●	●				●						●	●	●	●			●
Akuvio			●						●													
Alexera				●																		
Alligator Bioscience	●															●	●	●				
Alzecure Discovery		●											●			●	●					
Alzinova		●																	●			
Amniotics			●						●								●		●			
Anamar			●		●				●								●					
Annexin Pharmaceuticals							●									●						
Anocca	●																			●		
Apoglyx				●																		
Aprit Biotech	●					●																
Aptahem							●	●														
Aqilion	●				●																	
Asarina Pharma		●				●				●						●						
Ascelia Pharma	●															●	●		●			●
Asgard Therapeutics	●																		●			
Athera Biotechnologies							●									●	●					
Atrogi				●																		
Attgeno							●		●													
Beactica Therapeutics	●	●				●											●					
Betagenon Sweden	●	●	●	●			●			●						●						
Bioarctic		●														●						
Bioinvent International	●															●	●					
BTBPharma		●		●															●		●	
Buzzard Pharmaceuticals	●															●						
Calliditas Therapeutics			●		●											●	●		●			
Camurus	●	●					●		●	●			●			●			●			
Canimguide Therapeutics	●															●	●		●			
Cantargia	●				●		●									●	●	●				
Cellprotect Nordic Pharmaceuticals	●															●	●	●		●		

List of the 148 companies included in the report and a selection of 15 therapeutic areas in which they are active. We have also highlighted companies with projects in clinical trials, phases 0-III, Rare diseases and/ or in a selection of other relevant technologies such as Companion diagnostics, Drug delivery, Cell- and Gene therapy, Vaccines and Imaging, all representing areas of national strength and future promises.

Company	Therapeutic Areas															83	61	22	26	17	6	4	
	57	31	28	26	21	20	19	17	17	12	12	9	13	6	5								
	Oncology	Neurology	Inflammation	Endocrinology & Metabolism	Autoimmunity & Immunology	Obstetrics & Women's health	Cardiovascular	Infection	Respiratory diseases	Pain	Dermatology & Wound healing	Gastrointestinal	Other therapeutic areas	Ophthalmology	Transplantation	Projects in clinical phase	Rare diseases	Companion diagnostics	Drug delivery	Cell and Gene therapy	Vaccine	Imaging	
Cereno Scientific							●									●	●						
Cinclus Pharma Holding											●					●							
Cline Scientific			●																		●		
Combigene		●		●													●			●			
Corline Biomedical				●				●				●		●		●	●						
Curovir								●	●														
Cyxone		●			●											●							
Danpet	●	●					●																●
DexTech Medical	●					●										●	●		●				
Diamyd Medical				●												●	●	●					
Diaprost	●																	●					
Dicot												●											
Dilafor						●										●							
Dizlin Pharmaceuticals		●														●			●				
Double Bond Pharmaceutical	●							●	●							●	●		●				
Duttal				●																			
Ectin Research	●																						
Edvince		●					●										●						
Emplicure									●			●				●			●				
Empros Pharma				●												●			●				
Eurocine Vaccines						●		●								●			●		●		
Flora Innovation			●		●																		
Follicum				●						●						●							
Gabather		●														●							
Gedea Biotech						●		●								●							
Genagon Therapeutics	●					●												●					
Gesynta Pharma			●							●						●	●						
Glucox Biotech	●		●	●			●						●										
Guard Therapeutics International							●									●							
Gudna Pharma		●																					
Hamlet Pharma	●															●							
Hansa Biopharma	●				●							●		●		●	●						
Idogen					●										●		●			●			
Ilya Pharma			●							●	●					●				●			





*“The high proportion of projects that have the potential to be first-in-class reflects exciting scientific opportunities and innovative approaches being used by researchers to address critical unmet patient needs”*



# Status Pipeline 2020

*The current Swedish pipeline from discovery to Phase III consists of 420 R&D projects*

There has been a steady increase in the number of projects and companies reaching clinical stage throughout a decade of regularly monitoring the evolution of the Swedish pharma R&D pipeline. 2020 once again marks a milestone with a 14% increase in the total number of projects since our last report in late 2016.

This year we can report on 420 projects in discovery to phase III stages. Discovery and preclinical projects equate to 59% of the entire pipeline while 41% are reported to be in clinical trial, Phase 0 – Phase III. One third of the companies included in the report have only one project in their pipeline with the remaining two thirds having two or more.

## PROJECTS IN CLINICAL DEVELOPMENT

Fifty three percent of the companies run one or more projects in clinical phase I-III, comprising 148 projects in total. Also noteworthy is that as many as 24 projects have reached Phase III – this being the highest number ever reported in our series of pipeline reports.

In addition, 19 Phase 0 studies were reported by nine companies. Phase 0 is also known as exploratory investigational new drug

studies, and these trials intend to provide a better understanding of a new compound's pharmacokinetics, pharmacodynamics, and target localization before the initiation of Phase I trials.

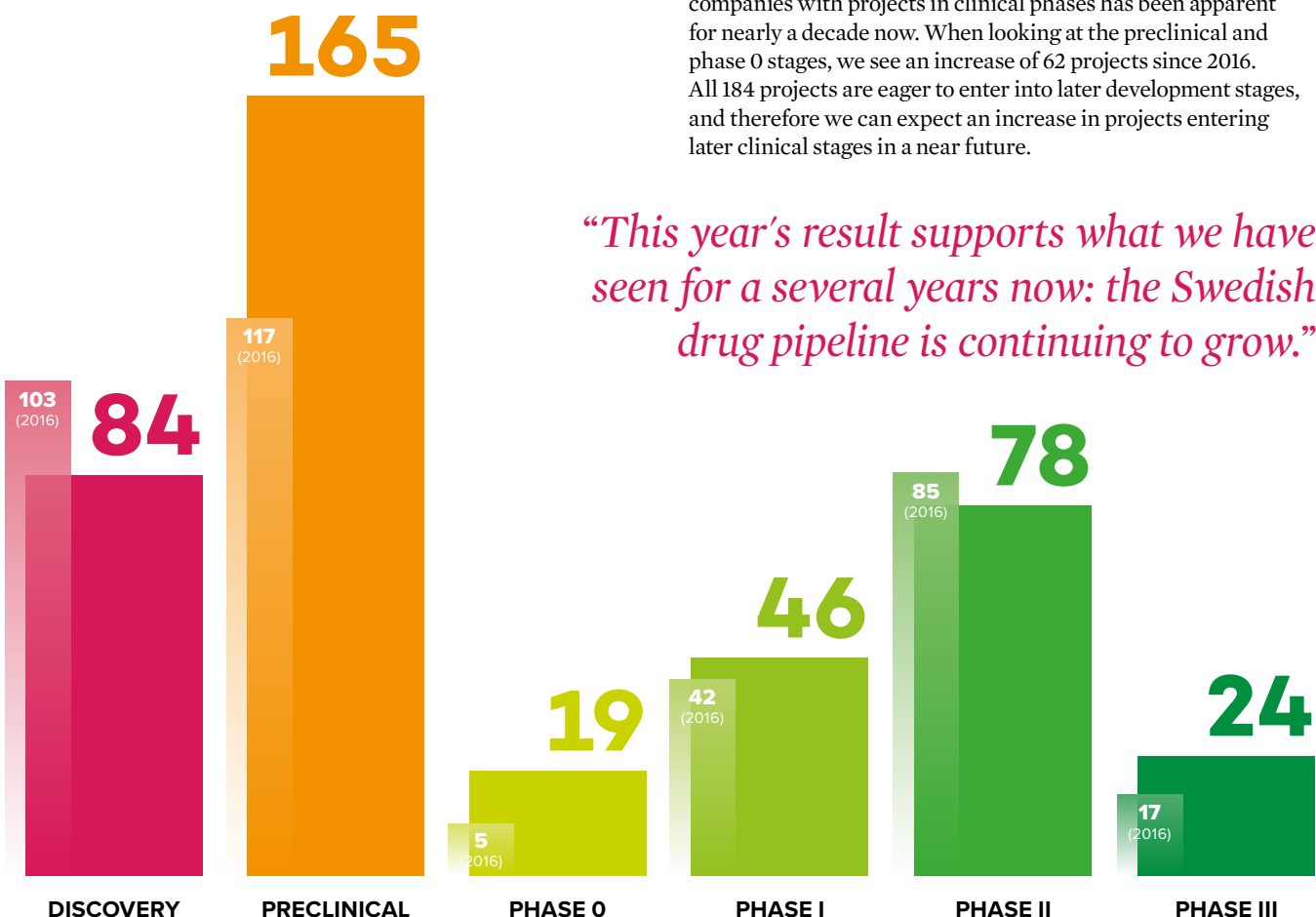
## FIRST-IN-CLASS

Potential first-in-class medicines represented more than 80% of the pipeline and 76% of the clinical pipeline (Phase I-III). First-in-class medicines are described as a unique pharmacological class distinctive from those of any other marketed products. Interestingly, 16 of the 24 Phase III projects would be first-in-class if approved during Spring 2020. In addition, 43 follow-on projects were recorded. Follow-on drugs have a similar chemical structure or the same mechanism of action as a drug that is already marketed, but may provide useful alternative or enhanced therapeutic options for patients or patient subpopulations.

## CONTINUED GROWTH

The latest pipeline report published in 2016 included 144 companies and 369 projects. At that time, 67 of the companies had one or several projects in clinical testing, totalling 144 projects in Phase I-III. This year, there are 79 companies with projects in clinical testing. This trend of a steadily increasing number of companies with projects in clinical phases has been apparent for nearly a decade now. When looking at the preclinical and phase 0 stages, we see an increase of 62 projects since 2016. All 184 projects are eager to enter into later development stages, and therefore we can expect an increase in projects entering later clinical stages in a near future.

*“This year’s result supports what we have seen for a several years now: the Swedish drug pipeline is continuing to grow.”*



Data source: See Material and Methods on page 39. No information for 4 projects was disclosed on stages of development and these are not included in this diagram.

## Type of compounds and development stages

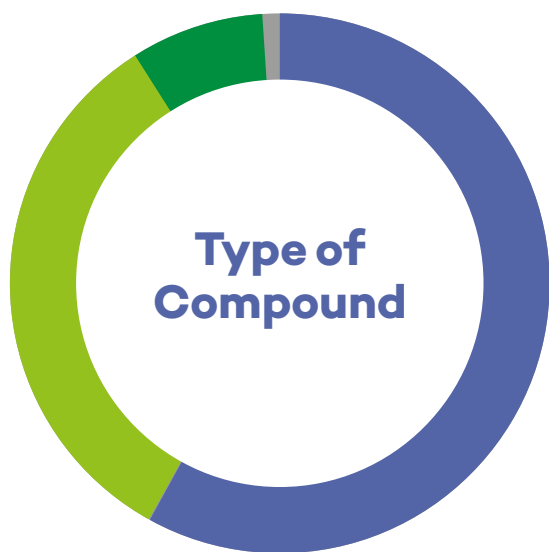
We can report on a total of 283 different compounds amongst the 420 projects. There are 112 different compounds in Phase I-III, and 31 of these are being tested in more than one project.

The majority, representing 76% of the compounds, are so-called new chemical/biological entries, i.e. a drug that contains an active moiety that has never been approved by the regulatory authorities.

Small molecules are the most common type of compound represented in the total pipeline, and they account for about 58% of all the compounds recorded here. This group includes both chemically synthesized compounds (149) and peptides.

The diverse group of biopharmaceuticals, i.e. antibodies (34), biologic peptides, proteins, vaccines, modified polysaccharides, DNA/RNA-based moieties, and live bacteria make up 33% of all compounds.

About 8% is accounted for by cell- and gene therapies, treatments based on tissue-engineering as well as genetically-modified bacteria.



**58%** Small Molecule  
**33%** Biopharmaceuticals  
**8%** Cell & Gene Therapy  
**1%** Undisclosed

Numbers and types of compound in different development stages from discovery to Phase III.

	Discovery	Preclin	Phase 0	Phase I	Phase II	Phase III
Small molecules	54	103	12	27	50	18
Biopharmaceuticals	21	44	7	16	21	6
Cell & Gene Therapy	9	18	0	3	7	0

## Hot numbers 2016 vs 2020



Projects from  
Discovery – Phase III



Companies with projects  
in Phase I-III



Compounds evaluated in  
clinical trials, Phase I-III



Projects in Phase III

## Phase III and beyond

This report presents 24 ongoing Phase III projects, which is the highest number ever recorded in a Swedish pipeline report. There are as many as 10 rare disease projects, five of which are directed towards treating rare haematological malignancies, with the other five directed at rare endocrinological, inflammatory and immunological conditions. Interestingly, we note that there are three companies as newcomers in the post Phase III stage: *AcuCort*, *Hansa Biopharma*, and *Palette Life Science / Pharmanest*. During 2019, each submitted their first market authorization applications. In addition, several Swedish companies with previously launched products, *Camurus*, *Oasmia Pharmaceuticals*, *Orexo*, and *Sobi*, have received approvals of new drugs in the last two years.

### POSITIVE RESULTS FOR PHASE III STUDIES

Phase III, the final stage of drug development prior to registration confirms the clinical doses, frequency, and timing of administration for approval. The overall success rate of phase III is around 70% and depending on the size can cost up to USD 100 million. Two companies had positive news to report in January 2020. *Moberg Pharma* announced that the expert evaluation of the results from the North American Phase III-study are now completed and the experts provide strong support for mob-15 as treatment for nail infection. Lipidor was shown to have positive top-line results of its Indian AKP01 Phase III clinical study, achieving its primary endpoint using calcipotriol spray against mild-to-moderate plaque psoriasis.

### SUBMISSION OF MARKETING AUTHORISATION

Once the phase III studies are completed and have delivered a positive outcome, compilation of the data to submit to the regulatory agencies begins. Filing a market authorization application (MAA) to the European Medicines Agency (EMA) or New Drug Application to the U.S. Food and Drug Administration (FDA) for registration is a key step in bringing a potential new therapy to the market. If approval is granted, the new therapy can then be sold for use as detailed in the final approval label granted by the regulatory authority. Three Swedish companies filed a MAA in 2019.

In 2019, *AcuCort* submitted a national hybrid application for approval of the company's drug candidate ISICORT® to the Swedish Medical Products Agency (MPA). ISICORT® is a regulatory bioequivalent with a reference product containing conventional dexamethasone tablets, a corticosteroid medication. It is used in the treatment of many conditions, including allergy and croup, but may also benefit cancer patients suffering from nausea and vomiting in connection with chemotherapy.

*Hansa Biopharma* submitted their MAA to the EMA for review of IDEFIRIX in 2019, as a treatment to enable kidney transplantation in highly sensitized patients. IDEFIRIX is a novel antibody-degrading enzyme that eliminates immunological barriers. It is administered as a single intravenous infusion immediately prior to transplantation and rapidly inactivates donor specific antibodies (DSAs).

*Palette Life Science* (formerly known as *Pharmanest*) submitted their MAA for review of Lidbree (SHACT) in 2018. Lidbree is a proprietary topical delivery technology that provides short-acting mucosal pain relief during placement of an intrauterine device.

### APPROVAL AND LAUNCH

When the marketing authorisation application approval is granted, the new therapy can then be sold for use as detailed in the final approval label granted by the regulatory authority. Several Swedish companies have received approvals in the last two years.

#### EARLY 2019

The Australian Therapeutic Goods Administration approved *Orexo's* Zubsolv® (buprenorphine and naloxone) for treatment of opioid dependence. Zubsolv is launched in the European Union and US and, in early 2020, it will be launched in Australia and New Zealand.

#### NOVEMBER 2018

*Camurus's* product Buvidal®/Brixadi™ (buprenorphin) was approved as the first long-acting injection for the treatment of opioid dependence in the European Union and Australia. To date, Buvidal® has been launched in seven countries, including Germany, the UK, and Australia.

#### NOVEMBER 2018

*Oasmia Pharmaceutical* received approval from the European Commission for Apealea® (paclitaxel micellar), for the treatment of adult patients with first relapse of platinum-sensitive epithelial ovarian cancer, primary peritoneal cancer, and fallopian tube cancer, in combination with Carboplatin. The product was launched in the Nordic countries in January 2020.

#### NOVEMBER 2018

*Sobi* received Approval from the European Commission and FDA for Gamifant® (emapalumab) for the treatment of primary Haemaphagocytic Lymphohistiocytosis. The product was launched in December 2018.

#### APRIL 2018

*Sobi* received approval from the European Commission for Kineret® (anakinra) for treatment of Still's disease. The product was launched in July 2018.

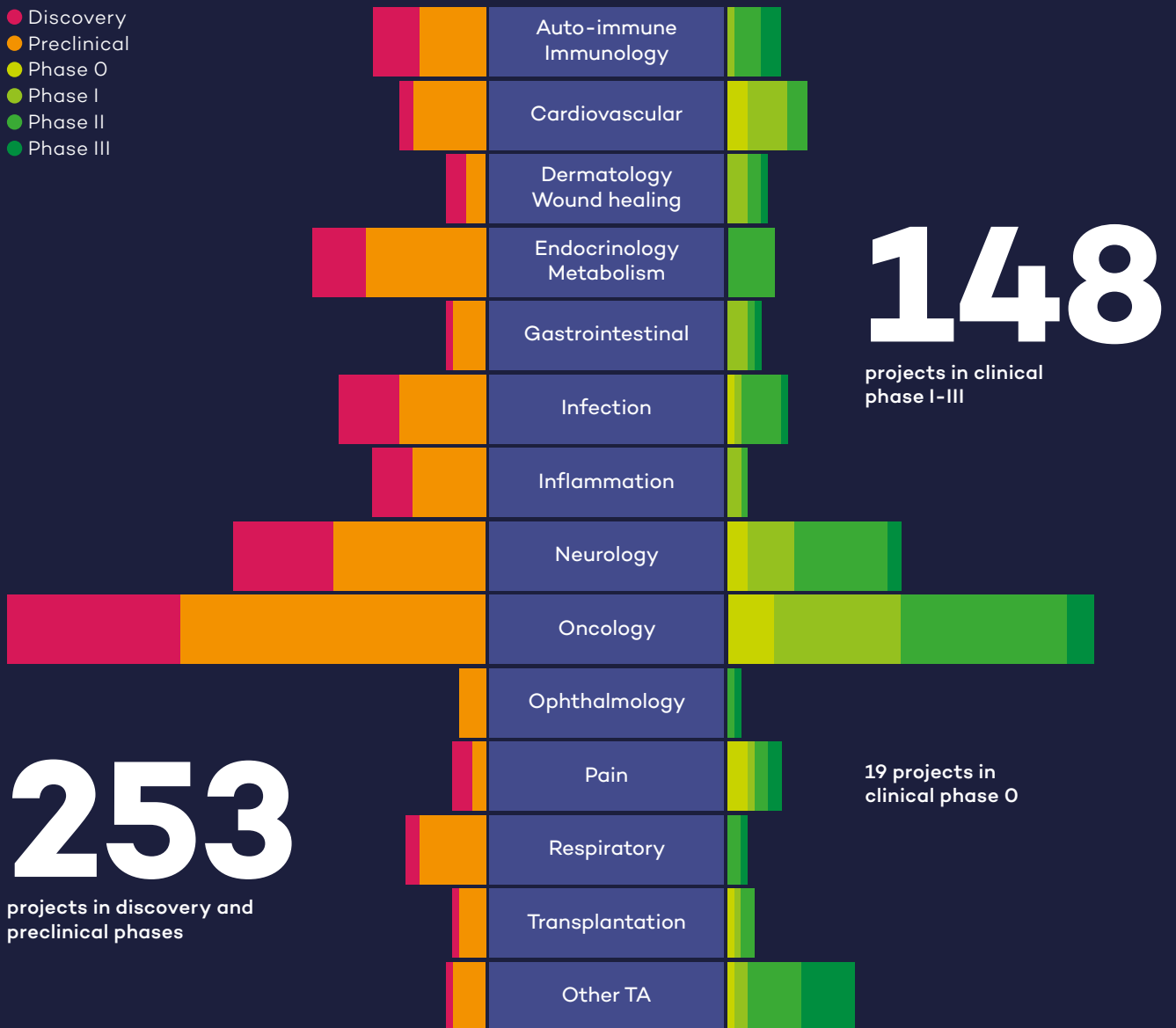
# Therapeutic areas

*Swedish companies are presently directing their efforts towards diseases in the top four therapeutic areas, oncology, neurology, endocrinology/metabolism and infection, with antibodies, or cell- and gene therapies in addition to the usual small molecule route.*

This report shows that the four most common therapeutic areas, both in early and clinical research stages, are predominantly oncology, neurology, endocrinology/metabolism and infection. This is in line with on-going research in the rest of the world as published in a recent report by Pharma Intelligence (Pharma R&D Annual Review 2019)

We note also that a high number of projects lie within the rare disease area and represent roughly 25% of the pipeline, with autoimmunology/immunology taking second place as the most popular therapy area behind the overall leader – oncology.

In addition to the above-mentioned therapeutic areas, others with strong pipelines in both preclinical and clinical stages are cardiovascular, inflammatory and respiratory diseases.



# Top four therapy areas at a glance



## ONCOLOGY

- 57 companies
- 128 projects representing 30% of the entire pipeline
- Most common projects: leukaemia, breast, liver, prostate, and colon cancers
- 48 projects are in phase I-III clinical stages, 4 projects in Phase III
- 2 preclinical projects with therapeutic vaccines to treat cancers
- 5 projects with diagnostic PET-ligands or contrast agents
- Swedish patients are included in 54% of the studies



## NEUROLOGY

- 29 companies
- 64 projects representing 16% of the entire pipeline
- Most common projects: Parkinson's disease, Alzheimer's disease, and psychiatric conditions
- 23 projects are in phase I-III clinical phases, 2 projects are in phase III
- 2 projects with therapeutic vaccines to treat Alzheimer's disease or multiple sclerosis
- 3 projects with diagnostic PET-ligands
- Swedish patients are included in 48% of the studies



## ENDOCRINOLOGY/METABOLISM

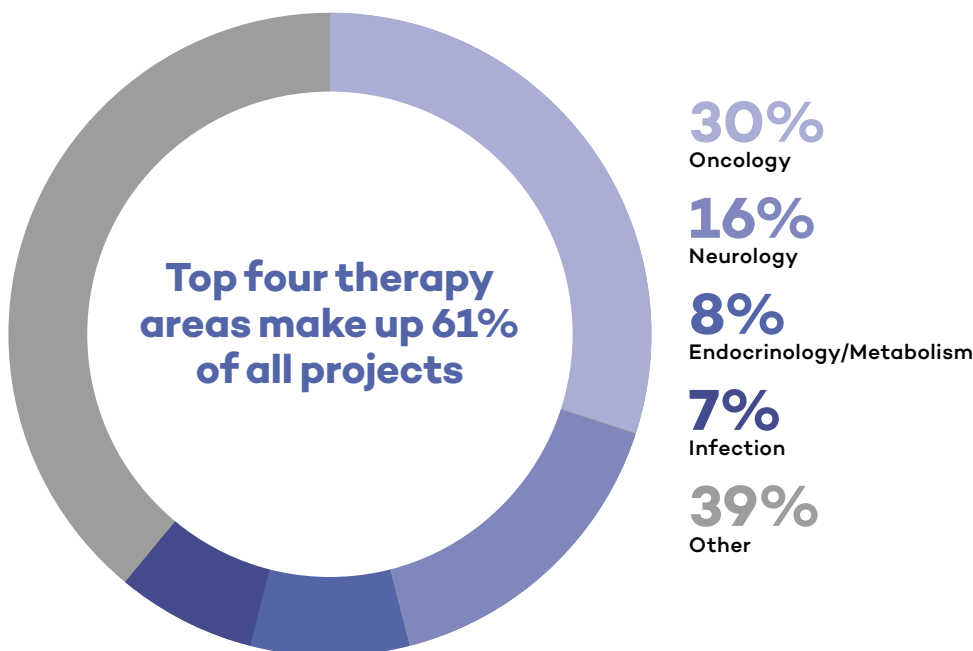
- 20 companies
- 34 projects representing 8% of the entire pipeline
- Most common projects: Type 1/Type 2 diabetes, and obesity
- 7 projects in clinical Phase II
- Swedish patients are included in 86% of the studies



## INFECTION

- 16 companies
- 31 projects representing 7% of the entire pipeline
- Most common projects: bacterial or viral infections
- 8 projects are in the clinical stages, 1 in Phase III
- 6 prophylactic and 2 therapeutic vaccines
- Swedish patients are included in 50% of the studies

→ For more information on the projects, please see the project list (Appendix)



## Indications

Subgrouping the projects in the different therapy areas reveals that many other indications are also popular targets. When specifically looking at projects that have reached clinical phase I-III, we see indications in wound healing / dermatology, pain, and gastrointestinal diseases in addition to the other major therapy areas.

### TOP 10 INDICATIONS IN CLINICAL PHASE I-III

Indication	Phase I-III
Parkinson's disease	8
Dermatology / Wound Healing	6
Pain	6
Gastrointestinal	5
Psychiatric conditions	4
Cancer, Leukemia	4
Cancer, Colorectal	4
Type 1 diabetes	4
Chemotherapy-induced malignancies	4
Infection, Viral	3



#### DERMATOLOGY/WOUND HEALING

The wound healing process is complicated and fragile, and susceptible to interruption or failure leading to the formation of non-healing chronic wounds. Factors that contribute to non-healing chronic wounds are diabetes, venous or arterial disease, infection, and metabolic deficiencies of old age.

Companies with projects in clinical stages in this area are: *Follicum*, *Ilya Pharma*, *Lipidor*, *Omnio*, and *Promore Pharma*.



#### PAIN

Stronger medications may be needed to relieve chronic pain. However, an over-prescription of opioid-based pain medications has led to a worldwide opioid-crisis – 8-12% of patients who are prescribed opioids over longer periods become addicted. In this report we note 9 companies developing non-opioid substances for the relief in patients suffering chronic pain.

Five companies have projects in clinical phases: *Moberg Pharma*, *Orexo*, *Stayble Therapeutics*, *Camurus* and *Klaria*.



#### GASTROINTESTINAL DISEASES

Currently, strong research interest for drug development in gastrointestinal diseases is focused on various inflammatory bowel diseases but also in other indications such as gastro-esophageal reflux disease, gastroparesis or prevention of necrotizing enterocolitis.

Companies with projects in clinical phases are: *InDex Pharmaceuticals Holding*, *OxThera*, *Cinclus Pharma*, *Nanologica*, and *Infant Bacterial Therapeutics*.

## Emerging technologies



#### CELL AND GENE THERAPY

26 cell therapies and 11 gene therapies are under development. Most of these therapies are used in oncological or neurological diseases but also in cardiovascular and inflammatory conditions.

For information on companies active in this area please see pages 36-37.



#### TRANSPLANTATION

There are a handful of companies working on projects aiming to improve both pre- and post-transplantation situations, in particular to minimize the frequency of rejection associated with transplantation of organs or cells.

Companies active in this field, both working with cell therapy techniques are *Idogen* and *Nextcell Pharma*. *Hansa Biopharma* is developing an enzyme that inhibits rejection, and is presently under late stage clinical investigation. *Corline Biomedical* and *Tikomed* are developing special types of modified polysaccharides to aid in transplantation procedures.



#### LIVE BIOTHERAPEUTIC PRODUCTS

A live biotherapeutic is a biological product that contains living microorganisms, such as bacteria, to prevent, treat or cure medical conditions, but is not classified as a vaccine.

Three companies, *Infant Bacterial Therapeutics*, *Metabogen* and *OxThera* are developing treatments based on live bacteria in 6 different projects, mostly for treating inflammatory conditions in the gastrointestinal tract. Three out of these projects are in clinical phase I or phase III. *Ilya Pharma* are using gene-modified bacteria (ATMP) in two projects for wound healing and gastrointestinal inflammation.



#### COMPANION DIAGNOSTICS

As many as 22 companies have or are developing a companion diagnostic in 43 different indications, see pages 20-23. Companion diagnostics are mainly being developed for oncological indications, but also for diabetic related diseases, infection, inflammatory conditions and a few in neurological diseases. 10 projects have already reached phase I-III stages giving promising opportunities for the development of precision medicines.

# Spotlight on immuno-oncology

*The field of immuno-oncology is evolving rapidly, and these treatments have emerged as an important therapeutic option for patients across many cancer forms.*

Immuno-oncology is a type of immunotherapy that is specifically targeted to fight cancer. It involves the body's immune system by mobilising lymphocytes to recognise and eliminate cancer cells, leaving the rest of the body unharmed. In theory, this is already much better for patients than the current treatments for cancer, which are principally surgery, chemo- and radiotherapy. It also has far fewer limitations, being applicable to tumours at all stages of the disease with much higher efficiency and lower recurrence rate.

Since the first immuno-oncology treatment was approved in 2010, it has proven effective in treating melanoma and lymphoma, as well as lung, kidney and bladder cancer.

In the pipeline, we can include over 20 companies using the immune system in various settings in the fight against cancer.



## CHECKPOINT INHIBITORS

Antibodies, peptides or small molecules can be developed into checkpoint inhibitors, directed to inhibit certain receptors, signal substances, etc, all important for survival or metastasis of the cancer cells. Examples include checkpoint proteins, regulatory T cells, but also other factors or hormones are being explored.

Companies running projects in this category are: *CanImGuide*, *Genagon Therapeutics*, *Hansa Biopharma*, *ISR Immune system regulation holding*, *Metacurum Biotech*, *Oblique Therapeutics*, *RhoVac*, *Sprint Bioscience*, and *WntResearch*.



## ACTIVATING THE IMMUNE SYSTEM

Activating certain immune cells enables them to attack cancer cells. These activated immune cells can then survive in the body and provide protection against metastases that may occur after completion of treatment.

*Alligator Bioscience*, *Active Biotech*, *Bioinvent International*, and *Cantargia* are all developing methods for targeting the tumour with an antibody and which the immune system's killer cells then become stimulated to destroy.



## CELL- AND GENE THERAPIES

Cell- and gene therapies have also found success in treating cancer. *Anocca* is individualizing the treatment by selecting certain types of T-cells that will kill the cancer in certain individuals. *Immunicum* and *TCER* are activating certain immune cells from healthy donors that when given to patients act by targeting the cancer.

*Asgard Therapeutics* and *Lokon Pharma* are using gene therapy to re-programme cancer cells to become immunogenic again, thereby making them vulnerable to the immune system.



## CANCER VACCINES

Cancer vaccines stimulate an immune response within the body to attack existing cancer cells. There are many types of cancer vaccines, and they typically contain either tumour antigens, cancer cell DNA or immune cell activators.

*2A Pharma* and *Abera Bioscience* are both working on the development of therapeutic cancer vaccines directed against specific tumour types.



## RADIOIMMUNO-THERAPY

Radioimmuno-therapy works by targeting the tumour with a protein or an antibody that has a radionuclide bound to it with aim of killing the tumour.

Companies developing this technology are *Affibody* and *Diaprost*.



*“Sweden has a long tradition in developing drug delivery solutions but also deep-seated experience in the new and exciting fields of cell- and gene therapy. Further, one fourth of the pipeline is addressing treatments of rare disease, a continued attractive field for Swedish companies”*



## Drug Delivery – Adding Value to Medicines

# Drug Delivery in Sweden

Drug delivery is the science of getting the right amount of active drug to the right place in the body at the right time. There are individual benefits to patients in having access to more effective and convenient ways to treat their diseases, and societal benefits in having improved treatments and better devices or packaging to improve adherence to and compliance with medication. Innovative drug delivery is more important than ever with the current trend towards more advanced therapeutic strategies, use of targeted approaches and precision medicine in addressing individual patient needs.

### TRADITION & SUCCESS

Sweden has a long history of excellence in drug delivery, reflected in the strength of this sector both in academic research but also in the successful development of products such as Symbicort Turbuhaler and Nicorette. Today we see a growing list of innovative Swedish companies with in-house and/or academic origin drug delivery solutions. Some of them also develop new drugs, including improved pharmaceuticals or addressing the challenge of finding solution to new modalities, from small molecules to cell therapies.

### NATIONAL ACADEMIC & INDUSTRY CENTRES

In the last few years, several drug delivery related, strategic longstanding partnership programs have been initiated and launched, involving the life sciences industry and research

organizations and universities: these are SweDeliver, Next BioForm and FoRmulaEx, all of which are focused on developing drug delivery of the future (see below for more information).

### SWEDEN DRUG DELIVERY INDUSTRY GROUP

To further boost drug delivery value creation, the Sweden Drug Delivery Industry Group was formed in 2016 with the objective to connect drug delivery players, communicate the value of drug delivery and to be a hub for the drug delivery industry sector. Today the group has 30 members, ranging from technology providers, service providers to drug developing companies. For more information, contact Jonas Johansson (Chairman): [jonas.johansson@astrazeneca.com](mailto:jonas.johansson@astrazeneca.com).

### Members of the Sweden Drug Delivery Industry Group

Technology providers	Service providers	Pharma
Affibody, Camurus, Disruptive Materials, Emplicure, Enza Biotech, ERCO Pharma, Grace, McNeil, Merck, Nanexa, Nanologica, Oasmia Pharmaceutical, Orexo, SHL Group, SOLVE Research, Vironova, Xspray	APL, Clinical Trial Consultants, CR Competence, FormulationWise, Galenica, Grace, Merck, Recipharm, SOLVE Research, TuuLifeScience, Vironova	Affibody, APL, AstraZeneca, Calliditas Therapeutics, Camurus, Disruptive Materials, Emplicure, Ferring Pharmaceuticals, Galenica, McNeil, Merck, Moberg Pharma, Nanexa, Nanologica, Oasmia Pharmaceutical, Orexo, Sobi, Vironova, Xspray

### FORMULAEX

#### CENTRE FOR FUNCTIONAL RNA DELIVERY

FoRmulaEx is contributing to fundamental knowledge required to succeed in the development of next generation nucleotide-based drug delivery.

All seven partners, including Chalmers University of Technology, University of Gothenburg, Karolinska Institutet, and with AstraZeneca as the leading company partner, jointly invest resources in the centre in order to carry out research projects with the objective to generate a more in depth understanding of drug formulation and the delivery process to enable new applications for nucleotide-based drug development.

The FormulaEx centre is administered and hosted by Chalmers, Department of Physics.

→ **Want to know more?**  
[www.chalmers.se/en/centres/FoRmulaEx](http://www.chalmers.se/en/centres/FoRmulaEx)

### SWEDELIVER

#### THE SWEDISH DRUG DELIVERY CENTER

SweDeliver is a drug delivery research network of highest international standard. The Centre is administered and hosted by Uppsala University, Department of Pharmacy.

The academic scientists have a strong track record in drug delivery, physical chemistry, biologics, pharmaceutical technology, and computational modelling & simulation.

Industrial members include e.g. Orexo, Affibody, Nanologica and Xspray and three global life science companies AstraZeneca, Ferring and Recipharm Pharmaceutical, which have complementary competences, unique materials, research infrastructure and the context of bringing products to the market.

→ **Want to know more?**  
[www.medfarm.uu.se/sddf](http://www.medfarm.uu.se/sddf)

### NEXTBIOFORM

#### CENTRE FOR FORMULATION AND PROCESSING OF BIOLOGICS

NextBioForm is providing cutting edge research on industrially relevant issues for formulation and characterisation of biologically based drug products, including biological pharmaceutical products, based on proteins and probiotics.

The focus is on improved product stability, development of new easy to use formulation platforms and excipients. The centre brings together 18 partners from the institute, academic, hospital and industry sectors, including, Lund University, Malmö University, Uppsala University Hospital, Sobi and MAX IV Laboratory.

NextBioForm is administered and hosted by RISE – research institutes of Sweden.

→ **Want to know more?**  
[www.ri.se/en/nextbioform](http://www.ri.se/en/nextbioform)

CASE STUDIES

## Swedish pipeline companies with innovative drug delivery technologies

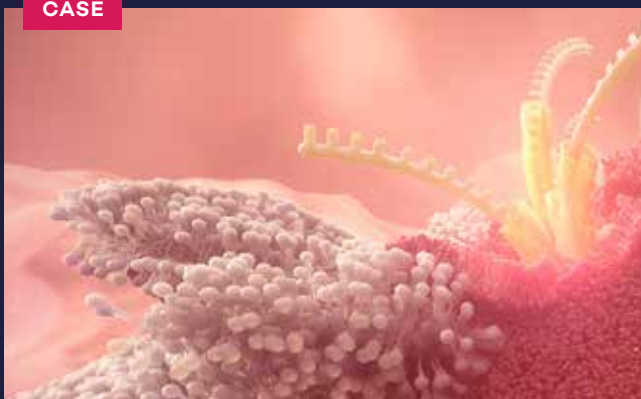
We have identified 26 companies with innovative, in-house and/or academic origin drug delivery solutions that also develops new drugs, see below. The methods and technologies being developed and used include both controlled and targeted drug delivery. Examples of these techniques range from nanoporous particles, lipids, oral films and long-term release formulations. Improved cancer treatment, pain and opioid dependence are examples of common therapeutic areas.

Interestingly, nearly half of the companies are based in Uppsala. The abundance of companies working with different approaches to new drug delivery techniques may be explained by the fact

that Uppsala University has a strong tradition of research within drug delivery. Also, research into new materials and nanotechnology is presently underway at Uppsala University, and as result there are a number of spin-out companies emanating from the university research and with focus on drug delivery.

Taken together, this is a group of rather mature companies, the majority have clinical stage projects, and several of the companies have launched products i.e. *Camurus, Lipidor, Moberg Pharma, Oasmia Pharmaceutical* and *Orexo*.

CASE



### DEVELOPING THE NEXT GENERATION OF DRUG DELIVERY TECHNOLOGIES

AstraZeneca aims to target any novel biology uncovered through developing an array of modalities. New advanced drug delivery systems are needed for targeted and controlled release of novel molecules in tissues and in cells to optimize their potential benefits for patients. Addressing drug delivery challenges is thus a substantial part of AstraZeneca's activities in Sweden.

AstraZeneca is actively engaged in collaborative efforts together with other stakeholders in the ecosystem, combining competences, infrastructure and resources to develop technology platforms and push the boundaries of science in Sweden. In FormulaEx, platforms to enable cellular uptake are explored and in SweDeliver novel technologies for both small molecules and biologics are developed. Such academia-industry collaborations accelerate development of future therapies and advances offerings by service and technology providers to global markets.

Scientists at AstraZeneca are for example developing a broad range of nanoparticles that aim to deliver new modalities to previously undruggable targets and precisely control their release in formulations that are easy to use and convenient for patients. They are also investigating innovative ways of getting oral formulations of biologic drugs across the intestinal wall – something which has eluded generations of drug designers.

→ Want to know more? [www.astrazeneca.se](http://www.astrazeneca.se)

INTERVIEW



Nikolaj Sørensen, CEO  
Orexo

### FROM UPPSALA AND AROUND THE WORLD FOUR TIMES

Orexo develops and commercialises improved pharmaceuticals therapies with a primary therapeutic focus around addiction, from prevention to treatment.

New innovative technologies are being developed for oral, sublingual and intranasal drug formulations.

Orexo's products have been approved in multiple markets and helped patients benefit from improved drugs worldwide. Localised in Uppsala, their own products are commercialized by Orexo in the US or via partners worldwide.

→ Want to know more? [www.orexo.com](http://www.orexo.com)

Company	Technology	Location
Acucort*	ISICORT®, is a thin, fast-dissolving, user-friendly oral film that melts on the tongue.	Helsingborg
Affibody*	Affibody® molecules, a novel class of antibody mimetics. Albumod™, enables modified/enhanced pharmacokinetics for biopharmaceuticals.	Solna
Alzinova	AβCC peptide™, research tools that enhance productivity within Alzheimer's disease research.	Göteborg
Ascelia Pharma*	Oncoral is a novel tablet-based formulation of the well-known chemotherapeutic agent irinotecan.	Malmö
BTB Pharma	Delivers disease-specific protein to the immune system, creating "tolerogenic cells". Adaptable to different autoimmune diseases.	Malmö
Calliditas Therapeutics*	NEFECON is an oral formulation of a potent and well-known active substance – budesonide – for targeted release.	Stockholm
Camurus*	FluidCrystal® - endogenous polar lipids spontaneously forming liquid crystal nanostructures in aqueous environments; at tissue surfaces or in the body.	Lund
Dextech Medical*	GuaDex - specific modified dextran molecules used as a backbone in constructions of new candidate medications.	Uppsala
Dizlin Pharmaceuticals*	Infudopa SubC® provides long-term continuous subcutaneous infusion via a small belt-pump.	Göteborg
Double Bond Pharmaceutical*	BeloGal® - a biomimetic encapsulation of the API with polymer- and biologicals-free excipient, protecting the remaining healthy tissues.	Uppsala
Emplicure*	Inhalation for early onset of effect of active substances. Micro-needle patch for drug delivery.	Uppsala
Empros Pharma*	A drug delivery technology that modifies release in the gastrointestinal system, maximizing the drug-effect and improving tolerability.	Stockholm
Eurocine Vaccines*	Endocine™ is a vaccine adjuvant, based on endogenous lipids naturally found ubiquitously in the human body.	Solna
Klaria*	An alginate-based polymer film. The film distributes the medication directly into the bloodstream.	Uppsala
Lidds*	NanoZolid® enables the controlled, long-term and personalized release of drugs for up to six months.	Uppsala
Lipidor*	AKVANO® - water-free, sprayable liquid formulations in which selected lipids and the active ingredient are dissolved in a volatile solvent.	Solna
Moberg Pharma*	Topical formulation of terbinafine	Bromma
Nanexa	PharmaShell®, drug particles are enclosed in a shell with controlled solubility	Uppsala
Nanologica*	NLAB Silica™ and NLAB Spiro™, two drug delivery platforms consisting of nanoporous particles where APIs can be placed inside the pores.	Södertälje
Oasmia Pharmaceutical*	XR17 platform enabling increased solubility of insoluble compounds. Based on a mixture of two derivatives (XMeNa and 13XMeNa) of vitamin A.	Uppsala
Orexo*	Sublingual drug delivery formulation platform, providing rapid onset and efficient absorption of the drug across the sublingual mucosa.	Uppsala
Quiapleg Pharmaceuticals	Uni-Qleaver® releasable pegylation, which allows a chosen release time for the drug through a controllable chemical coupling unit.	Uppsala
Salipro	The Salipro® technology allows reconstitution of purified membrane proteins either into lipid environment or into Salipro® particles.	Stockholm
Synartro	A platform enabling a sustained drug release. In combination with proven drugs it offers novel uses of existing drugs for human applications.	Uppsala
Uppsala Therapeutics	Cell-permeable, endosome escaping RNAi drugs, based on a proprietary cell-penetrating RNA design.	Uppsala
Xspray Pharma*	Xspray's patented nozzle make it possible to produce amorphous forms of drugs on a commercial scale that remain stable for a long time.	Uppsala

\* Projects in clinical trials, spring 2020.

# Cell & Gene Therapy in Sweden

*The Advanced Therapy Medicinal Products strategy in Sweden is nationwide engagement: together developing resources, infrastructure, competence and processes available to all*

Worldwide the gene and cell therapy product field are revolutionizing disease treatment, already showing marked efficacy to patients for whom treatments were previously not available. The novelty of these new pharmaceuticals is the gene and/or cell based active substances enabling pioneering of new ways to approach disease treatment for currently untreatable or incurable disease.

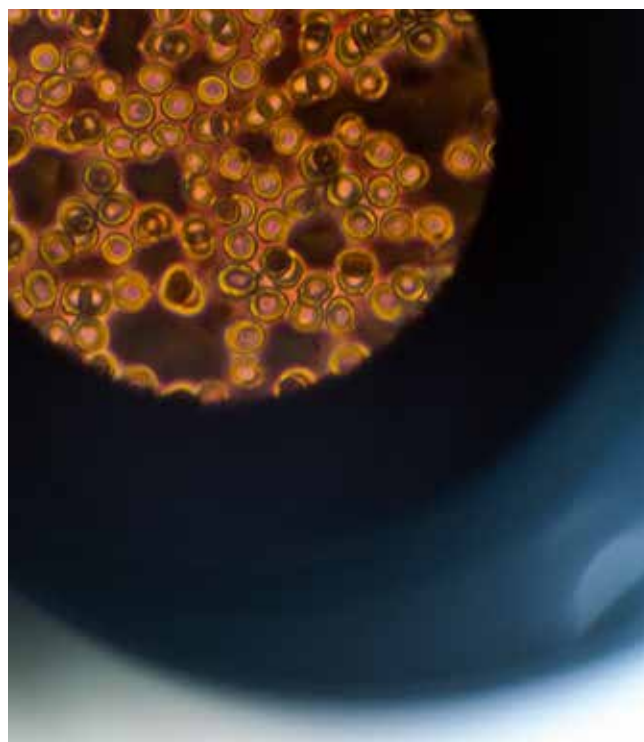
## ADVANCED THERAPY MEDICINAL PRODUCTS

Classified as Advanced Therapy Medicinal Products (ATMPs) by the European Medicines Agency (EMA), current gene and/or cell therapy products require the same stringency as traditional pharmaceuticals, including GMP manufacturing, clinical trials, market approval and reimbursement. However, often clinical trials for ATMPs are accelerated due to significant efficacious benefits for patients with limited options, meaning products can reach the market significantly faster than traditional drugs.

## NATIONAL STRATEGY

Sweden has committed to become world leaders in ATMP by 2030. Their strategy, nationwide engagement of ATMP stakeholders aims to spearhead the system level transformation required to support standard of care delivery of ATMPs. A large part of this means driving the development of new drugs, including precision medicine innovations in ATMPs. This commitment is a continuation of investment over the last decade to build world class GMP manufacture facilities at Sweden's University Hospitals, as well as current investment in the nation-wide initiatives Centre for Advanced Medical Products (CAMP), Swelife-ATMP and the ATMP Innovation Environment. Under the "ATMP Sweden" banner, these activities represent the core of a national inclusive network committed to generating the necessary collaborations, competence, innovations and system level transformations to make Sweden a world leader in ATMP by 2030.

*“Sweden gearing up to become a leader in development of and access to ATMP”*



## SWEDEN'S APPROACH TO BECOME A LEADER IN THE FIELD

- National inclusion; ATMP Sweden is the national 'one stop shop'. Not a single centre, company, town, state or region. Together, from bench to bedside, to reimbursement and nationally developing resources, infrastructure, competence and processes available to all.
- Integrating the patient perspective; engaging patient perspectives to build ATMPs, infrastructure, services and processes that make the patient the priority.
- Equal healthcare; Equal patient access means spreading resources and opportunities across the country. Sweden thrives on working together towards opportunities for all.

A solid government backing combined with Sweden's world-class research, research infrastructure, high quality healthcare, competitive business environment and world leading innovation has Sweden primed to succeed.

→ Want to know more or get involved? [www.atmpsweden.se](http://www.atmpsweden.se)

CASE STUDIES

# Swedish companies developing cell and gene therapies

In this survey we find 17 Swedish companies currently developing gene and cell-based therapies toward different indications. The techniques being used stretch from using gene therapies, different cell-based therapies, to whole tissue regeneration. Sweden's world leading position in innovation has translated to local academic spin out companies, of which six are currently in clinical trials with 10 different indications.

COMPANY	SPINOUT FROM
Amniotics	Lund University/Skåne Hospital
Anocca	Independent
Asgard Therapeutics	Lund University
CellProtect Nordic Pharmaceuticals*	Karolinska Institute/Karolinska Hospital
Cline Scientific	Chalmers University of Technology
CombiGene	Lund University
Idogen	Lund University
Ilya Pharma*	Uppsala University
Immunicum*	Sahlgrenska University Hospital
Lokon Pharma*	Uppsala University
NextCell Pharma*	Karolinska Institute
Procella Therapeutics	Karolinska Institute
Sinfonia Biotherapeutics	Independent
Svenska Vaccinfabriken Produktion	Independent
TCER	Karolinska Institute
Verigrant*	Karolinska Institute
Xintela	Lund University

\* presently have projects in clinical phase trials.

INTERVIEW



The three founders: Fábio Fiúza Rosa, Cristiana Pires, CEO and Filipe Pereira

## ASGARD THERAPEUTICS – GENE THERAPY

### FROM PORTUGAL TO LUND IN SWEDEN – FOLLOWING THE SCIENCE

In 2015, researchers at the University of Coimbra, Portugal, started working on a cell reprogramming approach to set in motion immune responses based on the unique properties of dendritic cells. While reprogramming approaches had been mainly restricted to regenerative medicine, this conceptual shift opens exciting opportunities to merge the fields of cell reprogramming and cancer immunotherapy.

– Filipe Pereira one of the co-founders, was head hunted by the Wallenberg Foundation to join as a fellow at Lund Stem Cell Center at Lund University and the Wallenberg Center for Molecular Medicine. So, we all followed the science and moved the lab to Lund University, says Cristiana Pires, CEO.

#### Tapping into the innovation system

– When we published the first results in 2018, we started the company with the support of LU Holding. We got support from LU Innovation with business advice and initial soft funding. This has been very valuable in strengthening and broadening our network, gaining the right competences on board, continues Cristiana.

#### What is special about the technology?

– The concept is to use transcription factors delivered by gene therapy to reprogram cancer cells. Usually cancer cells are really good at avoiding the immune system. With our approach, we force tumour cells to become visible again and induce an immune response against themselves. It's an off the shelf product but induces a response that will be very specific to the treated tumour, Cristiana concludes.

→ Want to know more? [www.asgardthx.com](http://www.asgardthx.com)

INTERVIEW



Mathias Svahn, CEO NextCell Pharma

## NEXTCELL PHARMA – CELL THERAPY

### FROM UMBILICAL CORDS TO DIABETES TREATMENT

NextCell Pharma develops ProTrans, a drug candidate consisting of stem cells for the primary treatment of auto-immune and inflammatory diseases as well as for prevention of organ transplant rejection. The company has developed a selection algorithm to ensure reproducibility and potency of ProTrans by carefully select cells for the manufacturing. NextCell also operates the stem cell bank Cellaviva, which has grown to be the largest cord blood bank in Scandinavia. The company is located at Karolinska Institutet Science Park in Huddinge, Stockholm.

*“The selection algorithm developed by NextCell enables us to produce the next generation of MSC cell therapy”*

→ Want to know more? [www.nextcellpharma.com](http://www.nextcellpharma.com)

# Rare diseases and orphan designation

*Swedish companies are committed to developing treatments for rare diseases. This is reflected by the fact that 26% of the Swedish drug pipeline targets rare diseases.*

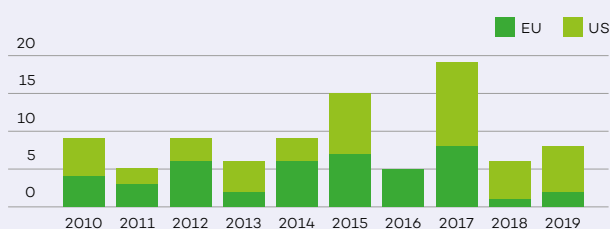
Resulting from our survey, we have identified 108 rare disease projects (from discovery to phase III), equalling 25% of the entire Swedish pipeline. In total, there are 46 projects in clinical phase I-III stages, equalling 42% of the rare disease projects.

During 2018 and 2019 ten Swedish companies were granted orphan designations for 12 different indications in the EU and/or the USA, as can be seen in the list below. In addition, Swedish Orphan Biovitrum (Sobi) received marketing authorisations for the orphan medicinal products Alprolix in 2016 and GAMIFANT in 2018.

Altogether, 60 companies included in this report have one or more rare disease projects and these are highlighted in the project list (please see the appendix).

*“In total, there are 46 projects in clinical phase I-III stages, equalling 42% of the rare disease projects”*

## ORPHAN DESIGNATIONS SWEDISH PROJECTS



During the period January 2000 to December 2019 Swedish research companies were granted a total of 62 orphan designations in the EU and 53 in the USA.

## ORPHAN DESIGNATION

A rare or an “orphan disease” is any disease which affects a small percentage of the population (5 in 10 000 people (EU) or ~ 6 in 10 000 (USA)). Granting of an orphan designation for a medicine will give the holder some benefits such as protocol assistance, fee-reductions or tax-credits. Once an orphan drug is authorised, it qualifies for 10-year market exclusivity in both the EU and Japan, and a 7-year market exclusivity in the USA.

### Swedish company holders of granted orphan designations in the EU and/or USA during the years 2018-2019

COMPANY	YEAR GRANTED		INDICATION
	EU	US	
Biolvent International	-	2019	Mantle cell lymphoma
Calliditas Therapeutics	-	2019	Primary biliary cholangitis
Calliditas Therapeutics	-	2019	Autoimmune Hepatitis
Hansa Biopharma	2018	2019	Anti-glomerular basement membrane disease
Hansa Biopharma	2018	2019	Guillain-Barré syndrome
Idogen	2017	2018	Haemophilia A
ITB-MED	2017	2018	Prevention of solid organ transplant rejection
NeuroVive Pharmaceutical	2017	2018	Inherited mitochondrial respiratory chain disease
PledPharma	-	2019	Acetaminophen overdose
Rare Thyroid Therapeutics	2017	2019	MCT8 deficiency (Allan-Herndon-Dudley-Syndrome)
Sarcomed	-	2019	Limb-girdle muscular dystrophy
Swedish Orphan Biovitrum	2019	-	Haemophilia A

# Materials and methods

In October 2019, SwedenBIO initiated an extensive search to identify companies active in the field of discovery and development of drugs for human use, using information from previous years' reports, databases, conference attendee lists, and our own database of member companies. We also contacted incubators, science parks and investment promotion agencies across the country in order to broaden the scope of the search for and identification of relevant companies.

We prepared an on-line survey and used a reference group of individuals with differing profiles and backgrounds to discuss and evaluate the survey prior to distribution of the complete company list.

During January and February 2020, we invited companies to participate in the survey and to provide answers to general questions about their company and also about any relevant technologies and information regarding their projects and products within the field of drug discovery and development. The invitation to participate was widely distributed and also included in several of our collaborators' newsletters in order to

reach out to an even wider network of companies. Follow-up phone calls were made to the recipients to present and inform about the initiative.

## Selection process and analysis

The data from the survey was collated and follow-up interviews were performed both by phone and e-mail to ascertain proper relevance to the drug discovery field, and also to complement survey answers. 127 companies responded to the survey, of which 8 were excluded due to the delimitations. Thorough web searches were performed to gather information on any relevant drug discovery and development companies that we did not manage to get in touch with.

## Selection of companies

We selected 148 companies based on the following criteria: stock companies; companies headquartered in Sweden; companies with research and development in drugs for human use; and companies with a business-to-business model. Service providers and business-to-consumer companies as well as medical device development projects were excluded.

## Data sources

The databases used were: The Swedish Industry Guide, ([www.swedishlifesciences.com](http://www.swedishlifesciences.com)), Biotechgate.com, SwedenBIO's member list ([swedenbio.se/members](http://swedenbio.se/members)), conference attendee lists e.g. from Nordic Life Science Days ([nlsdays.com](http://nlsdays.com)) as well as relevant company web sites. Incubators, science parks and investment promotion agencies were contacted to obtain more extensive information on companies. Corporate information was obtained from Allabolag ([www.allabolag.se](http://www.allabolag.se)).

Data from previous reports – The Swedish Drug Development Pipeline report -06, -07, -08, -09, -10, -11, -12, -13, -14, -15 and -16 were included for comparison.

**All reports can be downloaded from the SwedenBIO website: [www.swedenbio.se/pipeline](http://www.swedenbio.se/pipeline)**



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