



The Swedish Drug Discovery & Development Pipeline 2016

- INCLUDING A COMPANY OVERVIEW
- SPECIAL HIGHLIGHT ON WOMEN'S HEALTH
- EXCLUSIVE LIST OF 369 PROJECTS

DECEMBER 2016

THIS REPORT IS PUBLISHED BY SWEDENBIO WITH SUPPORT
FROM BUSINESS SWEDEN AND IN COLLABORATION WITH BULB INTELLIGENCE.

About the report

This report provides facts and figures about the current Swedish drug development pipeline for drugs intended for use in humans. The report serves as a quantitative indicator of the status and progress of Swedish drug pipeline compounds, projects and their characteristics.

The report has been produced annually since 2006 and is published by SwedenBIO, the Swedish Life Science Industry Organization (www.swedenbio.se).

This year we are proud to announce two new collaboration partners – Business Sweden, the Swedish Trade and Invest Council and bulb Intelligence – Business Competitive Intelligence Partner.

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Material and method

A list of relevant companies with projects in pre-clinical and clinical stage has been compiled. The list is based on last year's report, and has been supplemented with Swedish companies identified through database searches, examination of industry event participants and external environment monitoring. A search for companies in Swedish science parks and incubators was also carried out. Several companies were also contacted directly in order to confirm on-going R&D activities.

During October and November 2016, the companies were invited to participate in a web-based questionnaire about their current pipeline status.

In total, 91 companies responded to the survey. For the remaining companies, pipeline information was collected from sources such as last year's report, company websites, www.clinicaltrial.gov and by e-mail and telephone interviews.

The databases that were used include, but are not limited to, The Swedish Industry Guide, (www.swedishlifesciences.com), and company lists provided by bulb Intelligence based on SNI-codes. Corporate information, was obtained from Allabolag (www.allabolag.se).

Data from previous reports – The Swedish Drug Development Pipeline report -06, -07, -08, -09, -10, -11, -12, -13, -14 and -15 were included for comparison. All reports can be downloaded from the SwedenBIO website: www.swedenbio.se/pipeline

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INTRODUCTION

High R&D activity in Swedish biotech and pharmaceutical companies

The Swedish life science industry is constituted of 1 391 companies within all major sectors - pharma, biotech and medtech. Of these, around 890 are running research and development programs based in Sweden (Tillväxtanalys PM 2016:04).

This report highlights the Swedish companies that actively develop pharmaceutical drugs for human use. The report has been published annually since 2006 and aims to provide not only an up-to-date snapshot of the status of the industry, but also to map how the Swedish drug development pipeline is evolving over time with an overview of the companies with a Swedish base engaged in drug development.

This year, 144 Swedish companies falling into this category were identified, of which 67 have projects in clinical development.

The data presented in this report includes in-depth analyses of clinical phase I–III projects and an overview of preclinical projects. Background information on these companies is also presented including statistics on size, geographical location and number of employees.

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This year's edition also includes an exclusive list of all clinical and preclinical projects, covering the different compounds, indications and progression, in total 369 projects. This list can be found at the end of the report.

There are currently 144 projects in clinical development – an increase of 37 projects compared to last year. As noted in previous years, an accumulation of projects in phase II is clearly vis-

ible. Five companies that last year were running pre-clinical projects only now report projects in clinical phase I. This year Albireo and Camurus reported positive phase III studies and SOBI, Orexo and Oasmia have submitted applications and/or received marketing approval. Further information about this is available on page 9.

Oncology, CNS and gastro-intestinal are the therapeutic areas with the most projects in clinical development. There are now 43 oncology projects – an increase from 38 last year. Many companies also have projects aiming to improve women's health. Both clinical and pre-clinical projects across all indication areas are presented in more detail on page 14. Orphan diseases continue to be a focus area for Swedish companies. During 2015, ten projects received an orphan designation from EMA and/or FDA and 31% of the clinical projects are targeted towards an orphan disease.

When added together, the companies have around 1600 employees (based on data from 2015). All but one (SOBI) are small to medium-sized enterprises (SMEs).

Jonas Ekstrand
Director General, SwedenBIO



INTRODUCTION BY SWEDENBIO

SWEDEN – A STRONG LIFE SCIENCE NATION

Measured by the high level of business activities and the substantial financial resources recently raised by Swedish life science companies, this sector is presently experiencing exciting times, a fact further underpinned by the high numbers of companies with drug projects in both preclinical- and clinical phases as presented in this report.

Sweden is considered as one of the world's most prominent research nations. Our strong academic base and world-leading infrastructure for research form the basis for a successful and innovative life science industry. In particular, Sweden has a long tradition in the development of pharmaceuticals with leading examples such as Xylocaine, L-dopa, Omeprazole and Genotropin, to name a few.

There are many ongoing initiatives aimed at further strengthening the Swedish life science sector. For example, the Office for Clinical Studies (www.kliniskastudier.se) is coordinating the country's different resources to ensure that Sweden remains an attractive country in which to conduct clinical studies. In collaboration with SwedenBIO and Swedish Medtech, SweLife has devel-

oped The Swedish Life Science Database (www.swedishlifesciences.com), an information platform providing an extensive overview of key resources in our life science sector.

Policymakers benefit from facts and the purpose of The Swedish Drug Discovery and Development Pipeline Report, produced annually since 2006, is to monitor and describe, in quantitative and qualitative terms, the developments within the Swedish pharma sector. The report also serves as an invaluable source of information for companies, investors and other parties seeking collaboration and business opportunities in Sweden.

However, the most efficient way to come face-to-face with the Swedish life science community and its innovative companies is to attend SwedenBIO's annual investment, partnering and networking event – Nordic Life Science Days (www.nlsdays.com). This event will next take place on September 12–14, 2017 in Malmö – Copenhagen, at the heart of the Medicon Valley.

We are grateful to our partners for making the production of this report possible and wish you as a reader an informative and enjoyable insight into the world of Swedish drug discovery and development.

About SwedenBIO

SwedenBIO is the national association for the life science industry in Sweden. Our 220 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!**

Ulrika Cederskog Sundling
Executive Vice President
Invest & Region Sweden



INTRODUCTION BY BUSINESS SWEDEN

BUSINESS SWEDEN – A GATEWAY TO BUSINESS WITH SWEDEN

Business Sweden helps international companies expand their business in Sweden through entering into strategic partnerships or investing in Swedish companies. We connect global companies with business opportunities in Sweden and provide them with the information, guidance, solutions and network required to invest in Sweden.

Life science is Sweden's second largest export industry, with pharmaceuticals having an export value of 6 billion euro (2013), making this sector a strategic priority for the Swedish government. Backed by a strong tradition in life science, particularly in pharmaceutical research and development, Sweden wants to stay at the forefront of advances in this sector.

This annual report produced by SwedenBIO, the Swedish Life Science Industry Organization, highlights the status of Sweden's drug discovery and development pipeline. It is not only an important tool for the ongoing monitoring of the state of the industry, but also a valuable instrument for promoting the strength, focus and attractiveness of the Swedish drug discovery and development pipeline for collaboration and investments.

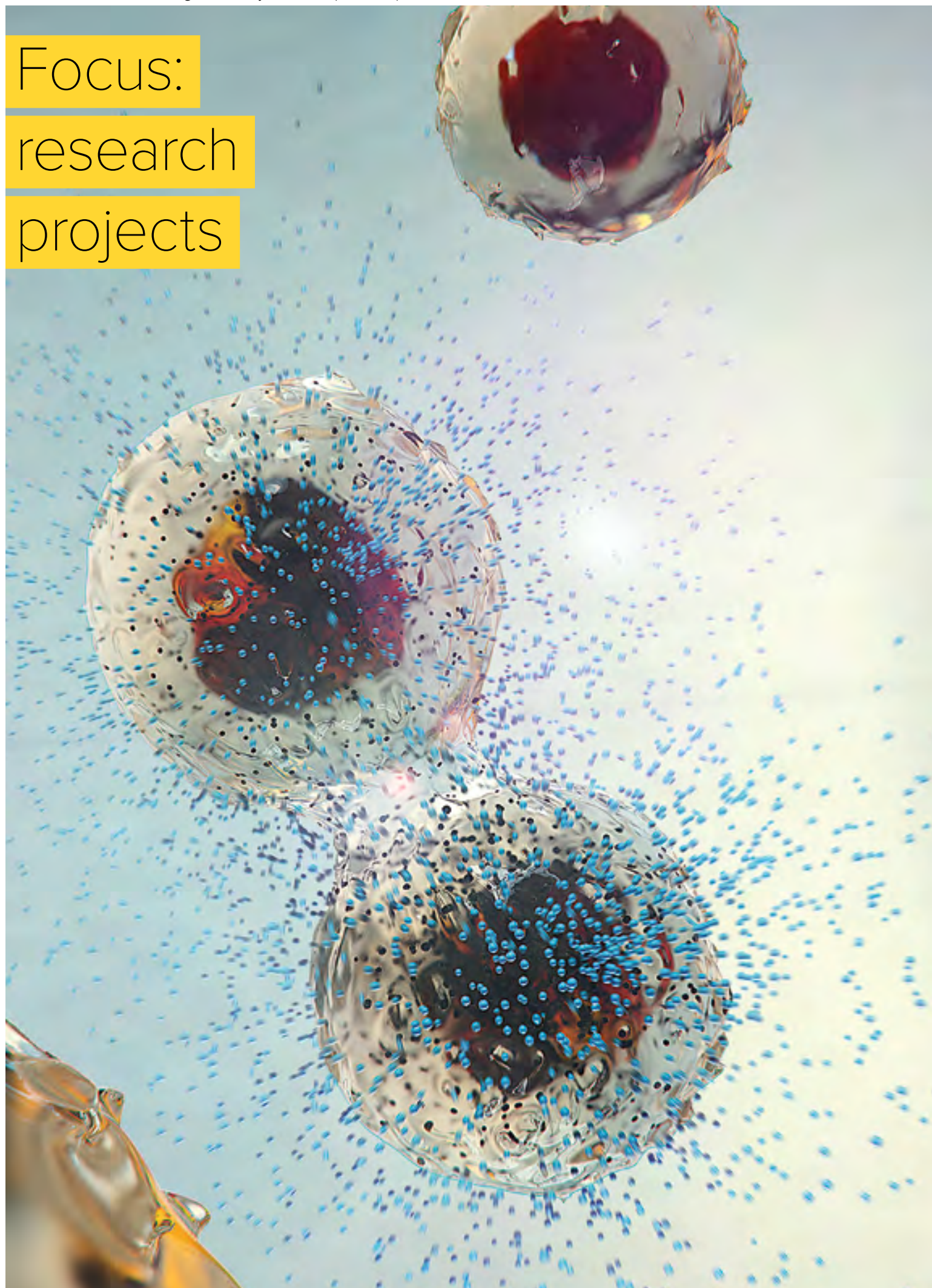
It is not only an important tool for the ongoing monitoring of the state of the industry, but also a valuable instrument for promoting the strength, focus and attractiveness of the Swedish drug discovery and development pipeline for collaboration and investments.

About Business Sweden

Business Sweden's purpose is to help Swedish companies reach their full international potential and foreign companies to invest and expand in Sweden. We offer our customers strategic advice and hands-on support.

Business Sweden is co-owned by the Swedish Government and industry partners, an association that provides ideal access to contacts and networks at all levels in the sector and industry. Business Sweden was founded on the first of January, 2013, by a merger of the Swedish Trade Council (Exportrådet) and Invest Sweden. **Visit us at www.business-sweden.se.**

Focus: research projects

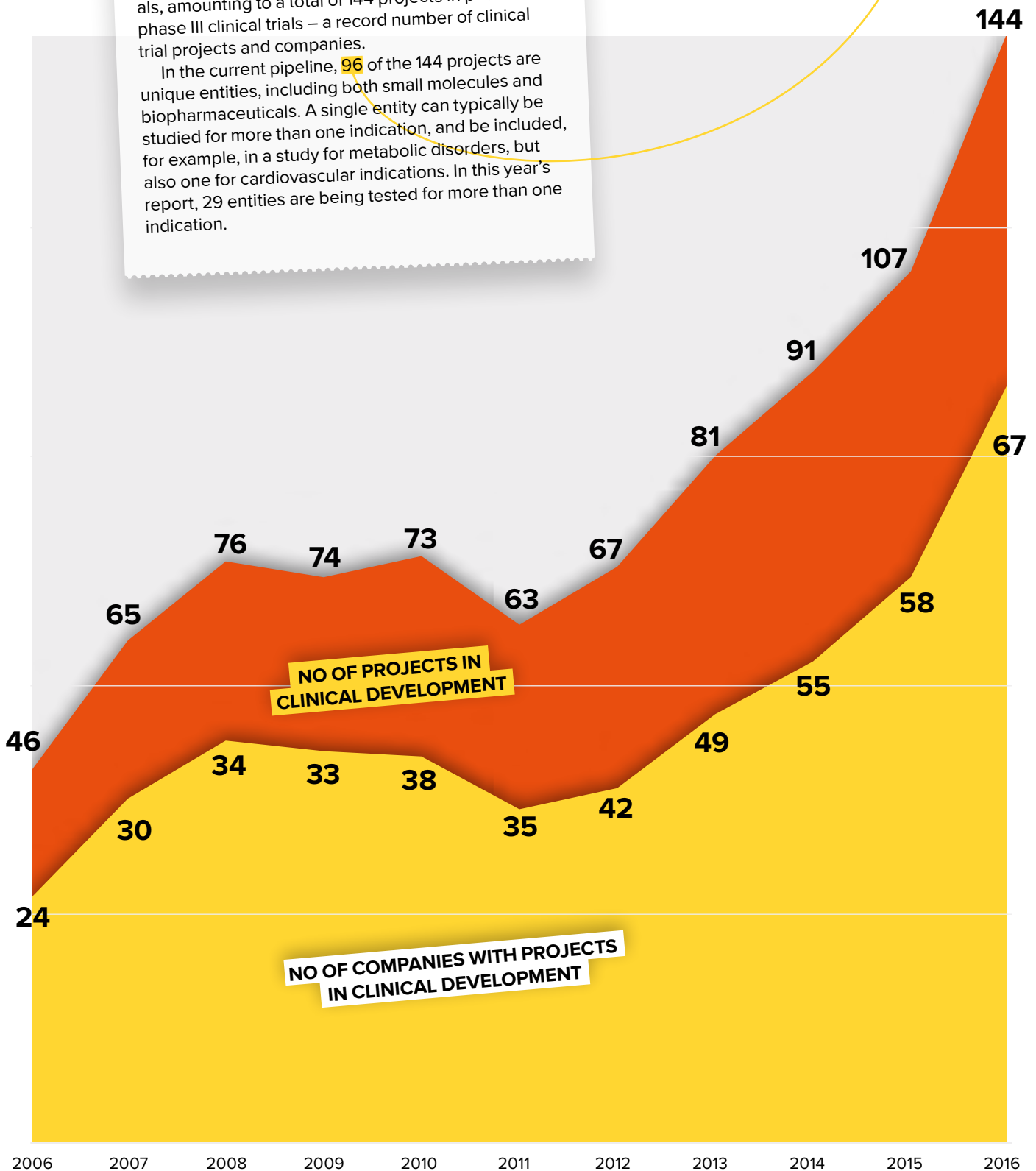


NUMBER OF COMPANIES AND PROJECTS IN CLINICAL TRIALS

This year's pipeline report includes 67 companies that have one or more projects in clinical trials, amounting to a total of 144 projects in phase I to phase III clinical trials – a record number of clinical trial projects and companies.

In the current pipeline, 96 of the 144 projects are unique entities, including both small molecules and biopharmaceuticals. A single entity can typically be studied for more than one indication, and be included, for example, in a study for metabolic disorders, but also one for cardiovascular indications. In this year's report, 29 entities are being tested for more than one indication.

96
unique
entities in clinical trials



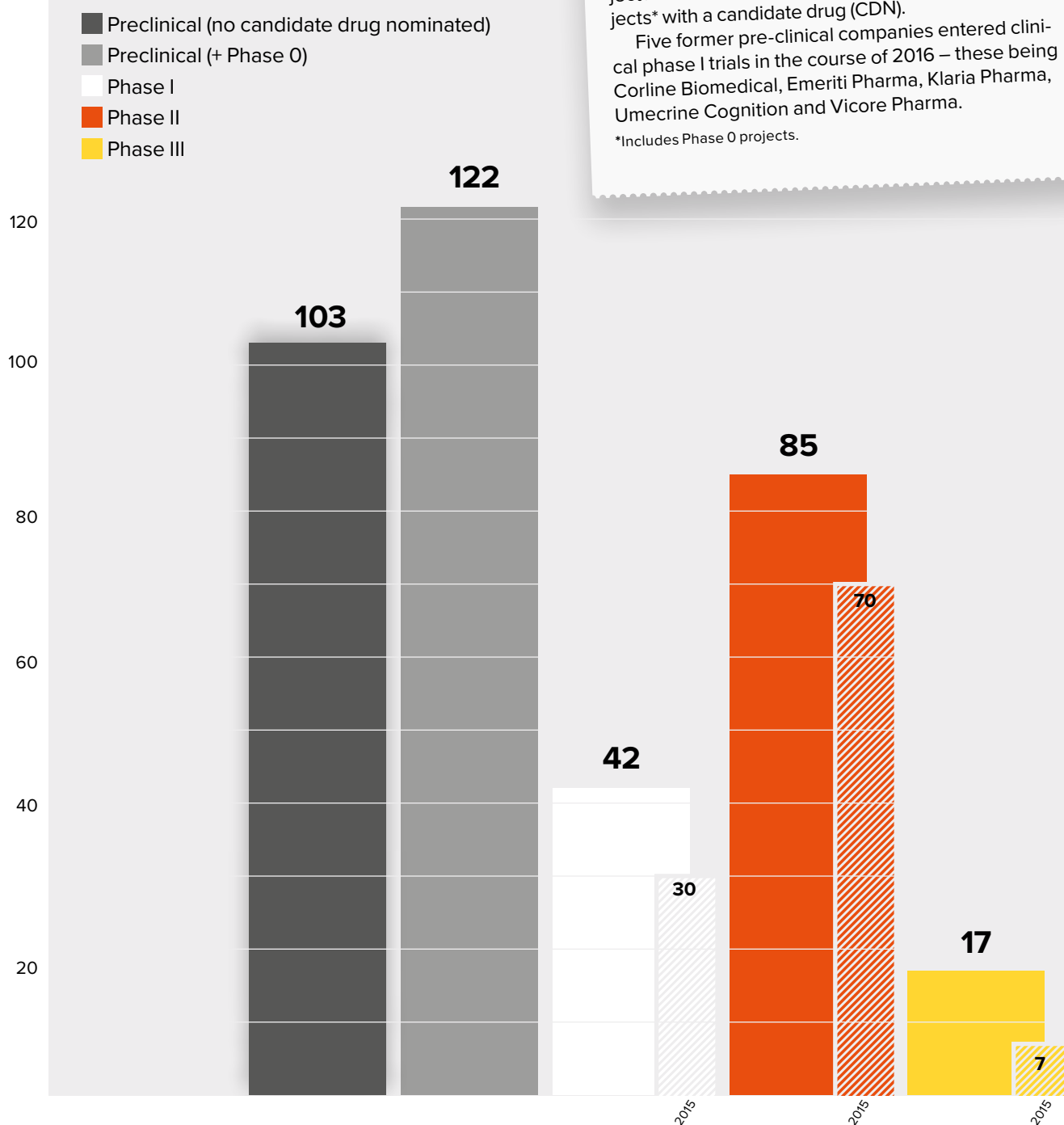
Source: web-based survey, public databases, company webpages and company interviews

ONGOING PROJECTS AND APPROVED PRODUCTS

This year, the number of projects in the respective phases are reported as being 42 (30) projects in phase I, 85 (70) in phase II and 17 (7) in phase III. Compared to last year, there has been a substantial increase of projects across the board. As in previous years, the majority of the projects are found to be in phase II, and this number has increased from 70 to 85 projects. Starting with this year's report, the number of preclinical projects is also being reported and amounts to 103 projects without a candidate drug (No CDN) and 122 projects* with a candidate drug (CDN).

Five former pre-clinical companies entered clinical phase I trials in the course of 2016 – these being Corline Biomedical, Emeriti Pharma, Klaria Pharma, Umecrine Cognition and Vicore Pharma.

*Includes Phase 0 projects.



Source: web-based survey, public databases, company webpages and company interviews.

Status phase III projects

This year we report 17 projects in phase III. Six projects have progressed from phase II since last year, five are ongoing and six have been completed, are waiting for additional studies to be completed, or are looking for a partner in order to be developed further. Both Albireo and Camurus recently reported positive results on their studies.

**NOV
2016**

Camurus and Braeburn Pharmaceuticals announced positive top-line results from a pivotal phase III trial of weekly and monthly injections of buprenorphine (CAM2038) for treatment of moderate-to-severe opioid use disorder.

**OCT
2016**

Albireo announced positive top-line results from a pivotal phase III clinical trial of its product candidate, elobixibat, in chronic constipation conducted in Japan.

Marketing Authorization Application (MAA) and Approval

Filing a Market Authorization Application (to EMEA) or New Drug Application (FDA) for registration is the next step in bringing a potential new therapy to the clinic. 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. Since the last report, Oasmia Pharmaceutical has submitted two applications. Orexo and SOBI received approval for four products.

**OCT
2016**

Orexo received approval from the US Food and Drug Administration (FDA) of a new unique low dose, 0.7 mg/0.18 mg tablet of Zubsolv (buprenorphine/naloxone) sublingual tablet (CIII) for the treatment of opioid dependence.

**JUN
2016**

SOBI announced approval from the Food and Drug Administration of a higher strength 20 mg capsule of Orfadin® (nitisinone) for the treatment of Hereditary Tyrosinaemia type-1 (HT-1).

**MAY
2016**

SOBI and Biogen announced approval from the European Commission of Alprolix® (rFIXFc), their extended half-life therapy for the treatment of haemophilia B in all 28 European Union member states and maintained its orphan designation. In October 2016, the product was also approved in Switzerland.

**FEB
2016**

Oasmia Pharmaceutical submitted an MAA to the European Medicines Agency (EMA) for its lead cancer product Apealea (also known as Paclical). The application is based on results from a phase III study on epithelial ovarian cancer.

**JAN
2016**

Oasmia Pharmaceutical submitted an MAA of Doxophos for Russia and the Commonwealth of the Independent States (CIS). The product is a novel formulation of one of the most widely used anti-cancer substances.

**NOV
2015**

SOBI announced approval from the European Commission of Elocta® (rFVIII Fc) for the treatment of haemophilia A in all 28 European Union member states, as well as Iceland, Liechtenstein and Norway. In June 2016, the product was also approved in Switzerland.

ONCOLOGY DRUGS STILL A PIPELINE PRIORITY

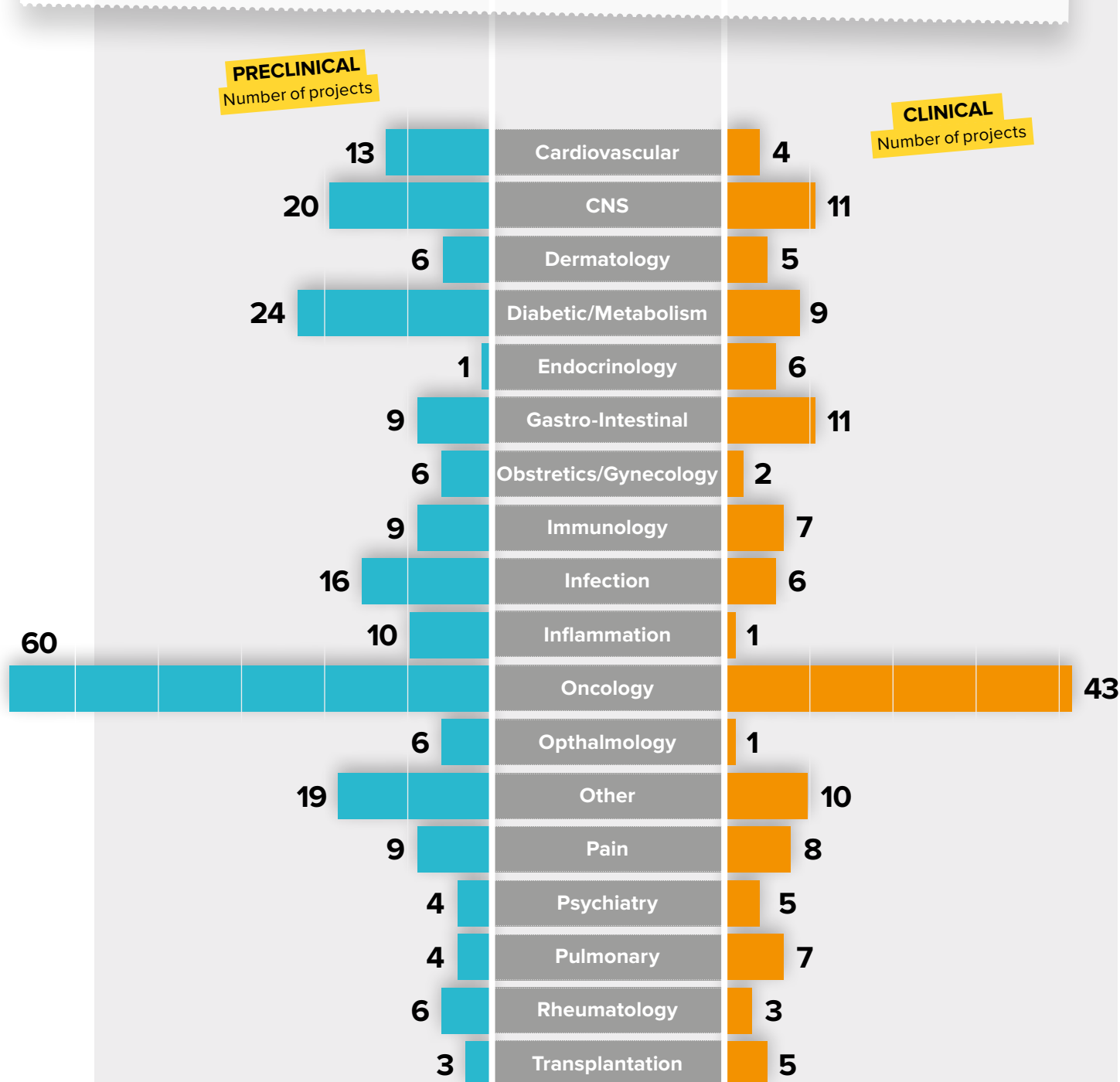
Oncology is one of the largest therapeutic areas in terms of drug development activity, addressing a disease area that causes more deaths than all other diseases put together, with the exclusion of cardiovascular diseases.

The Swedish clinical pipeline is dominated by oncology projects, with 43 projects (38 last year) equal to 30% of the clinical pipeline. Other strong areas are CNS and gastro-intestinal each with 11 projects. The category "Other" includes projects in the areas of haematology, nephrology, and undisclosed diseases etc.

Similarly to last year, small molecules comprise the majority of the clinical projects in the pipeline at 50% of the compounds. 27% is represented by a group of large

molecules that includes antibodies, therapeutic vaccines, cell therapies and hormones. A hybrid class of peptides corresponds to 10% of the compounds. The remaining percentage is made up of molecules/entities either classified as others or undisclosed.

This year we also requested information on preclinical projects and these are now also included in the analysis. Oncology projects dominate in this group, but we now additionally see diabetes/metabolism, CNS, infection and cardiovascular diseases developing as strong areas. The preclinical data is less extensive but give an indication about the future potential of these areas.

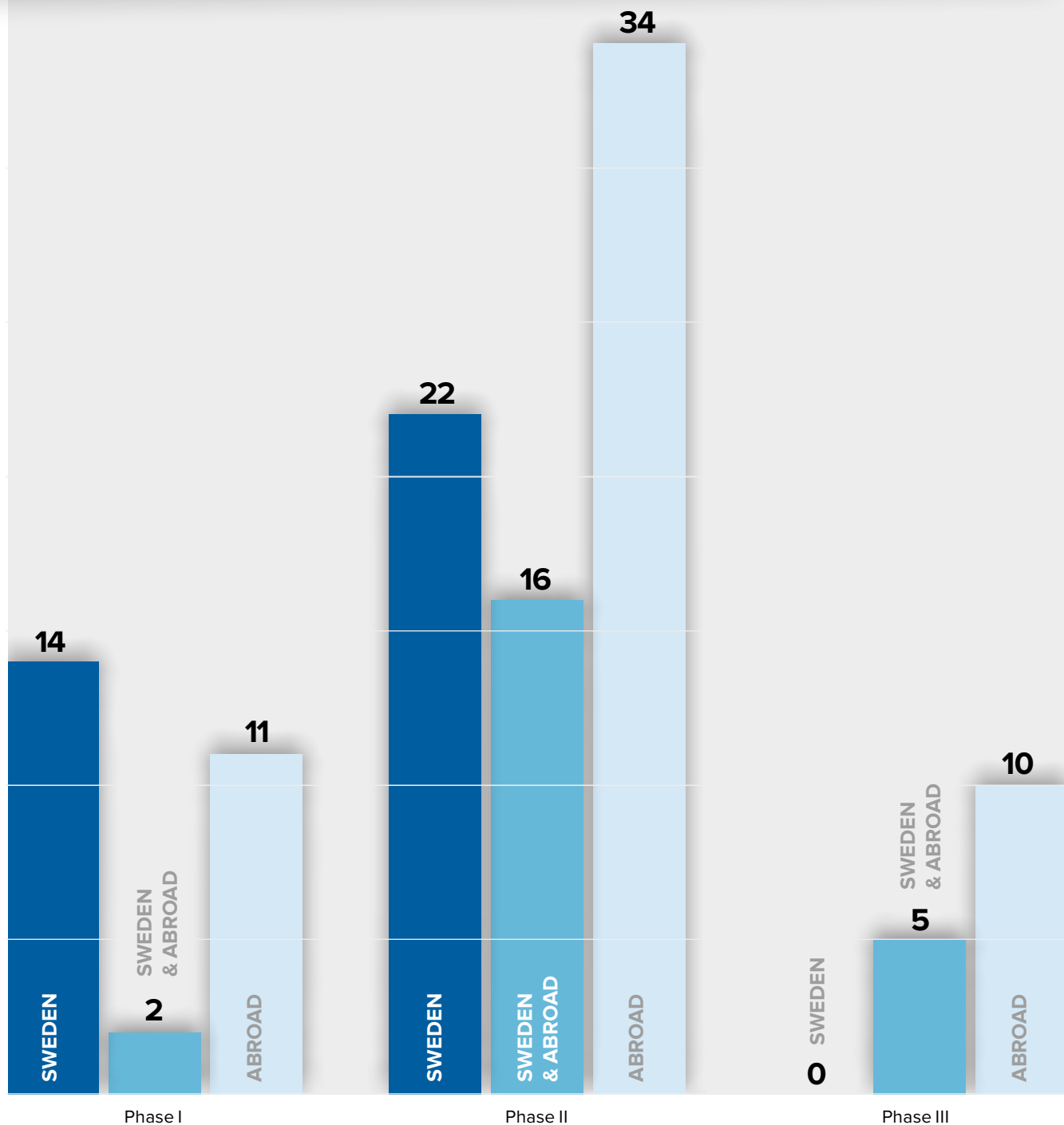


SWEDEN – POPULAR FOR CLINICAL TRIALS

Swedish drug development companies act on a global market and to choose to perform their clinical trials in Sweden is not a given fact. However, about half of the companies presented in this report include Swedish patients in their studies and one third of the trials are conducted in Sweden only, confirming the country's strong international position.

Recently, Clinical Studies Sweden (Kliniska Studier Sverige) was established by the government to further improve conditions for conducting high quality clinical studies in Sweden. National support and coordination will make Sweden an even more attractive choice for clinical studies. The advantages are many:

- **Access to high quality clinical studies** is necessary for the development of life science companies working in the Swedish market
- **Patients receive earlier access to new treatments** and can contribute with their knowledge and experience
- **Participation in clinical trials contributes to professional development of the staff** as it provides information on new treatments
- **Ability to work with clinical trials is a competitive advantage to attract and keep competent staff**, and regions that are involved in clinical trials have a higher quality of care.



Source: web-based survey, public databases, company webpages and company interviews.
This graph shows data from 114 out of 144 projects where location for clinical trials could be found.

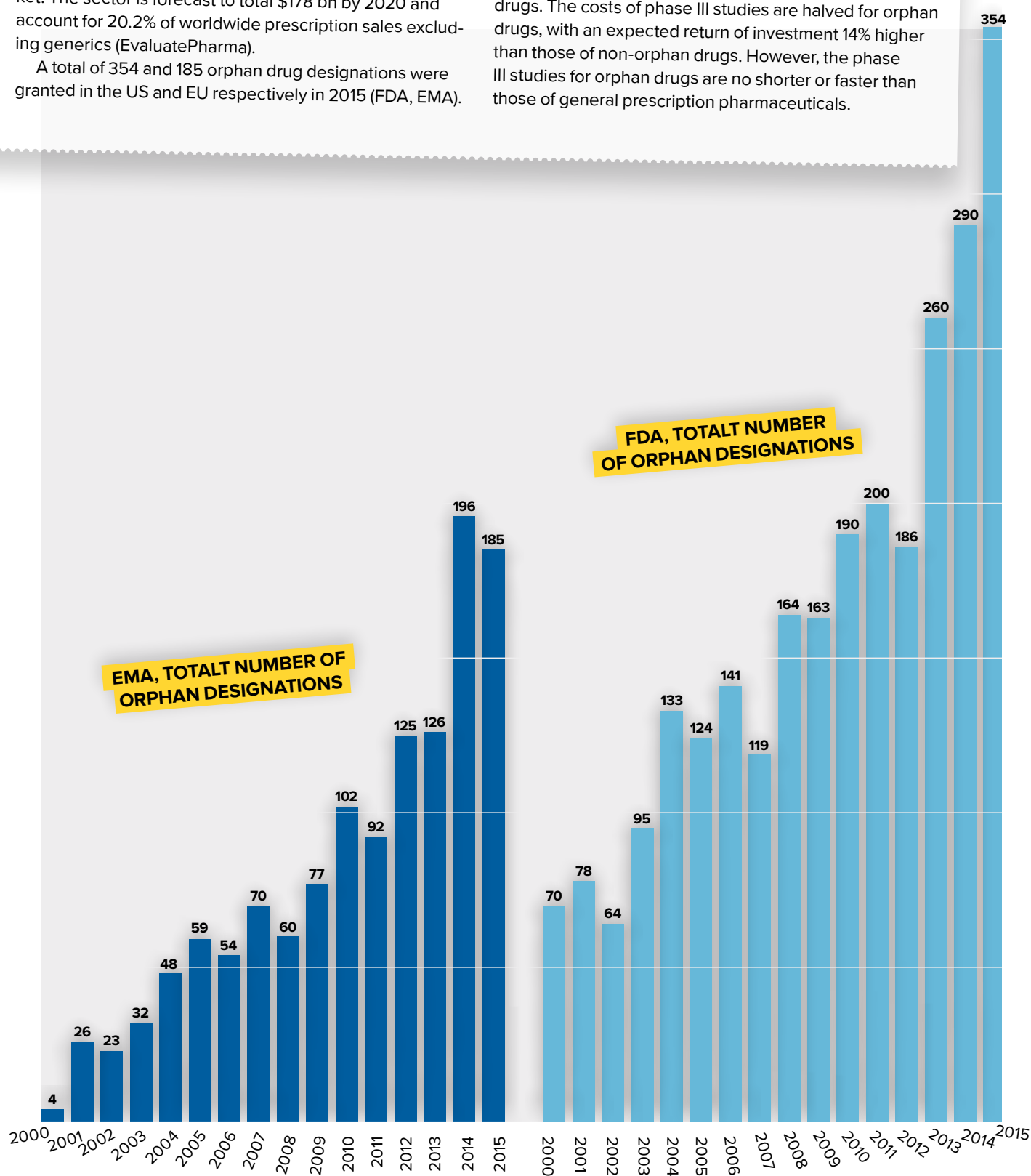
ORPHAN DRUGS ON THE RISE

Global trend

The tremendous interest in the orphan drug sector remains strong throughout 2015 with an annual growth of 12%, compared to the 6% growth of the prescription market. The sector is forecast to total \$178 bn by 2020 and account for 20.2% of worldwide prescription sales excluding generics (EvaluatePharma).

A total of 354 and 185 orphan drug designations were granted in the US and EU respectively in 2015 (FDA, EMA).

Despite the low prevalence of rare diseases (5/10000 – EU definition) they remain hugely profitable with a median cost per patient of 13.8 times the cost of non-orphan drugs. The costs of phase III studies are halved for orphan drugs, with an expected return of investment 14% higher than those of non-orphan drugs. However, the phase III studies for orphan drugs are no shorter or faster than those of general prescription pharmaceuticals.



Source: EMA, FDA, company web pages and Orphan Drug Report 2015, EvaluatePharma.

31%
of the clinical
projects

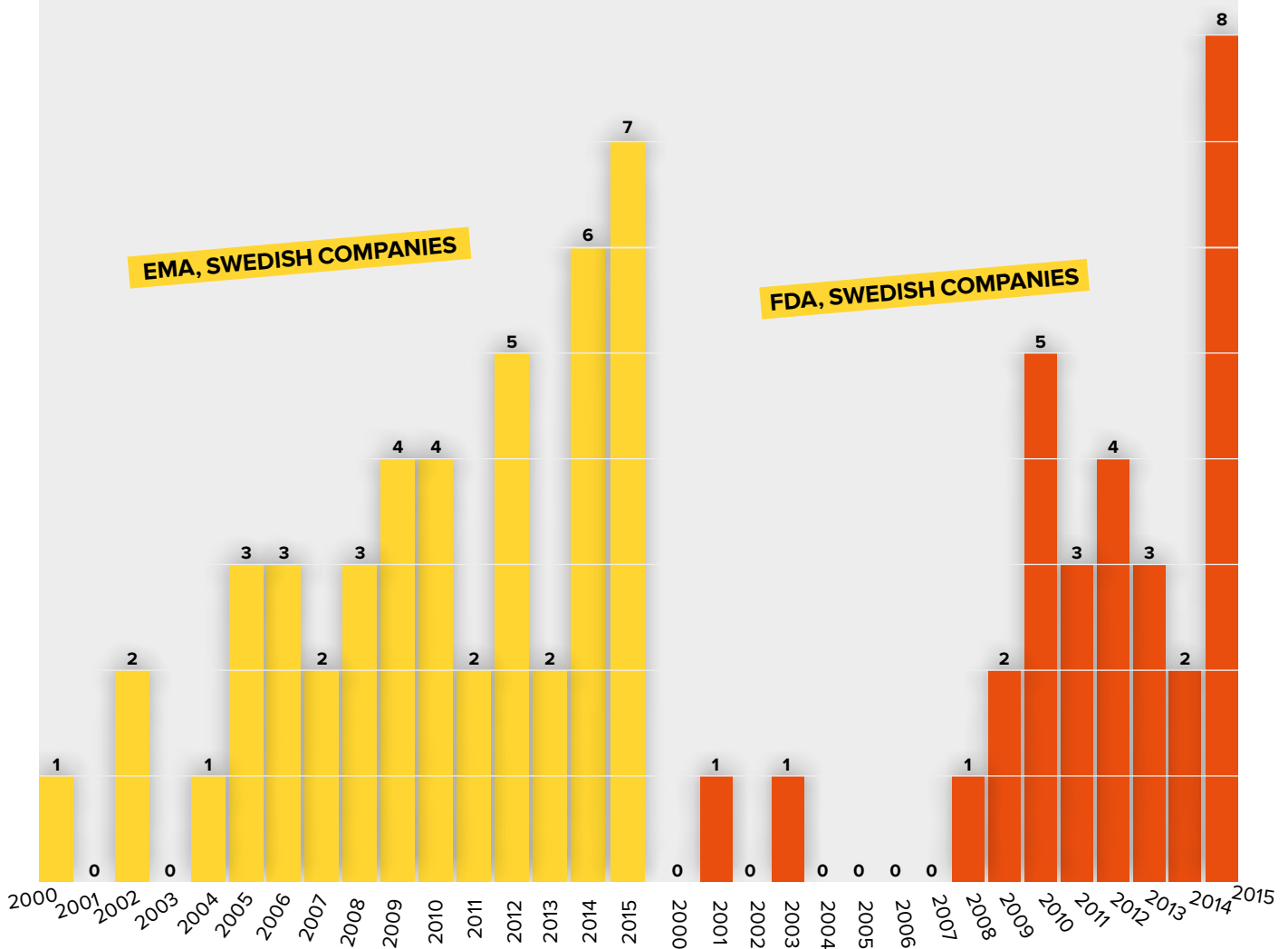
Swedish companies

According to the drug development pipeline survey 2016, 45 of the projects in phase I–III target an orphan indication, accounting for 31% of the clinical projects. Since 2000, 70 orphan drug status designations have been granted in total to Swedish companies by the EMA and FDA. In 2015, a total of ten Swedish companies received orphan drug designations granted by EMA and/or FDA, a record year with 8 designations by FDA.

- **Clanotech:** for prevention of scarring after glaucoma surgery.
- **Dilaforette:** for sevuparin sodium for the treatment of sickle cell disease.
- **Double Bond Pharmaceutical:** for doxorubicin for the treatment of hepatoblastoma.
- **Hansa Medical:** for the prevention of antibody mediated organ rejection in solid organ transplant patients.
- **Infant Bacterial Therapeutics:** for *Lactobacillus reuteri*

for the prevention of necrotising enterocolitis, with solid organ transplantation.

- **Lokon Pharma:** for modified adenovirus serotype 5/35 containing a CMV promoter-driven transgene cassette with the human transgenes for a membrane-bound CD40 ligand and full length 4-1BBL for the treatment of pancreatic cancer.
- **Oncopeptides:** for melphalan flufenamide for the treatment of plasma cell myeloma.
- **Sixera Pharma:** For the treatment of Netherton syndrome.
- **Swedish Orphan Biovitrum:** for Still's disease.
- **Toleranzia:** for fusion proteins composed of a genetically modified cholera toxin subunit A1, peptides from the acetylcholine receptor alpha chain and a dimer of the D fragment from *Staphylococcus aureus* protein A for the treatment of myasthenia gravis.



Source: EMA, FDA, company web pages and Orphan Drug Report 2015, EvaluatePharma.

SPECIAL HIGHLIGHT THIS YEAR ON WOMEN'S HEALTH

The Swedish pipeline includes several research projects, both in preclinical and clinical development, targeting women's health. This year's report brings a showcase of projects within gynaecology, obstetrics, breast and ovarian cancer and more.

Medical conditions affecting women generally represent high unmet medical needs, and have so far mainly been limited to alleviating symptoms. General awareness of these conditions is typically low, leaving many not properly- or uncared-for patients. Premenstrual dysphoric disorder (PMDD), a severe form of premenstrual syndrome is one example where – despite the high prevalence of the condition and the severity of its symptoms – the treatment options are few and the effect of treatments suboptimal.

A total of 17 companies are engaged in 22 women's health projects, of which more than half of the projects have their origins in academic research. There is currently one initiated phase III study – on pain relief during intra-uterine device (IUD) placements. Moreover, seven phase II studies are in the pipeline targeting e.g. dry eye disease, protracted labor, hirsutism, ovarian cancer, PMDD, pain relief during gynaecological interventions and vaginal atrophy.

Swedish projects with focus on women's health

THERAPEUTIC AREA	INDICATION	COMPOUND
Gynecology	• Chlamydia infection	• Chlamydia OMV Vaccine
	• Heavy menstrual bleeding	• N/A
	• Not decided yet	• UC2018
	• Pain relief during IUD placements	• SHACT , 4 lidocaine
	• Pain relief during other outpatient setting gynecological procedures	• SHACT , 4 lidocaine
	• Premenstrual dysphoric disorder	• UC2016
	• Premenstrual dysphoric disorder	• Sepranolone (UC1010)
	• Vaginal Atrophy	• Oxytocin
	• Dystocia/Protracted Labor	• Tafoxiparin
Obstetrics	• Preeclampsia	• A1M
	• Premature ovarian failure	• N/A
	• Breast cancer	• Deocecal
Oncology	• Breast cancer, metastatic	• Apealea/Paclical
	• Breast cancer, triple negative	• SB01328 and SB01683
	• Breast cancer	• Foxy-5
	• High Grade Serous Ovarian Cancer (Platinum-Resistant)	• APR-246
	• High Grade Serous Ovarian Cancer (Platinum-Sensitive)	• APR-246
	• Ovarian cancer	• NOV202
	• Ovarian cancer	• Melflufen
	• Hirsutism	• FOL-005
Other	• Melasma	• EP0003
	• Dry eye disease	• Small molecule

17

Swedish companies engaged in women's health.

22

ongoing projects in preclinical and clinical development.

12

projects in clinical development, phase I–III.

8

projects within oncology (breast cancer and ovarian cancer).

7

projects within gynecology.

3

projects within obstetrics.

COMPANY	PARTNERING STATUS	PRE-CLINICAL NO CDN	PRE-CLINICAL CDN	PHASE I	PHASE IIA	PHASE IIB	PHASE III
Abera Bioscience	Available						
Emeriti Bio							
Asarina Pharma							
Pharmanest							
Pharmanest							
Asarina Pharma							
Asarina Pharma							
Peptonic Medical	Available						
Dilafor							
A1M Pharma							
Follitech							
Oasmia Pharmaceutical							
Oasmia Pharmaceutical							
Sprint Bioscience	Available						
WntResearch	Available						
Aprea							
Aprea							
Noviga Research	Available						
Oncopeptides							
Follicum	Available						
Emeriti Pharma							
Redwood Pharma	Available						

Source: web-based survey, public databases and company webpages.

Anna Sandström
Director Science Relations AstraZeneca



AstraZeneca:

A GLOBAL PLAYER WITH HIGH PRESENCE IN SWEDEN

AstraZeneca is a global innovation-driven biopharmaceutical company with a strong presence in Sweden. The number of employees in Sweden at the end of 2015 amounted to a total of 6600.

At AstraZeneca, we follow the developments in science, and Gothenburg is one of our three global, strategic R&D centers. Today the site has 2,500 employees, which represents about 22.5 percent of AstraZeneca's total R&D force. At the site, we have 600 PhDs, 350 foreign researchers from almost 50 countries and 30 professors. In Södertälje, south of Stockholm, AstraZeneca has created one of the world's largest drug manufacturing centers. It is also the home of our Nordic-Baltic marketing company. The medicines delivered from Swedish operations represent more than 35% of AstraZeneca's total sales value - or 44 bn SEK in 2015. This represents about 3.7% of the total Swedish export of goods and makes AstraZeneca one of Sweden's most important export businesses.

CEO Pascal Soriot says "In 2015, we announced plans to invest more than \$285 million in a new manufacturing facility for biologics in Sweden. This was a strategically important investment for AstraZeneca to support the accelerating development of biotech medicines, which now make up around half of our pipeline".

The company is engaged in Swedish academic research through several joint-research collaborations. Our largest collaboration is with Karolinska Institutet, but we also have extensive collaborations with for instance Science for Life Laboratory, Gothenburg University, Sahlgrenska University Hospital, Chalmers and the Wallenberg centre for protein research at KTH.

► **University of Gothenburg and Chalmers University of Technology:** In the fall of 2015, AstraZeneca entered into a new collaboration on advanced mass spectrometry equipment. In this way, industry and institutions jointly engage in ground-breaking research.

► **High-technology facility for the manufacture of biopharmaceuticals:** In May 2015, AstraZeneca announced that a 285 million USD investment is to be made in a new high-technology facility for the manufacture of biopharmaceuticals. The new facility in Södertälje will focus on filling and packaging of biopharmaceuticals, and is expected to deliver drugs to the company's clinical trial programs from the end of 2018.

► **BioVenture Hub:** The BioVenture Hub gives emerging biotech/medtech companies and academic groups from Sweden and abroad a unique opportunity to co-locate with- and tap into - the power

of AstraZeneca's world-class scientists and state-of-the-art lab facilities and infrastructure, and with each other.

► **Karolinska Institutet:** The Karolinska Institutet/AstraZeneca Integrated Cardio Metabolic Centre that was initiated 2013, is AstraZeneca's most extensive ever contract with an academic institution. During the five-year initial contract period, AstraZeneca will contribute up to USD 100 million. The centre is to focus on both pre-clinical and clinical studies.

About AstraZeneca

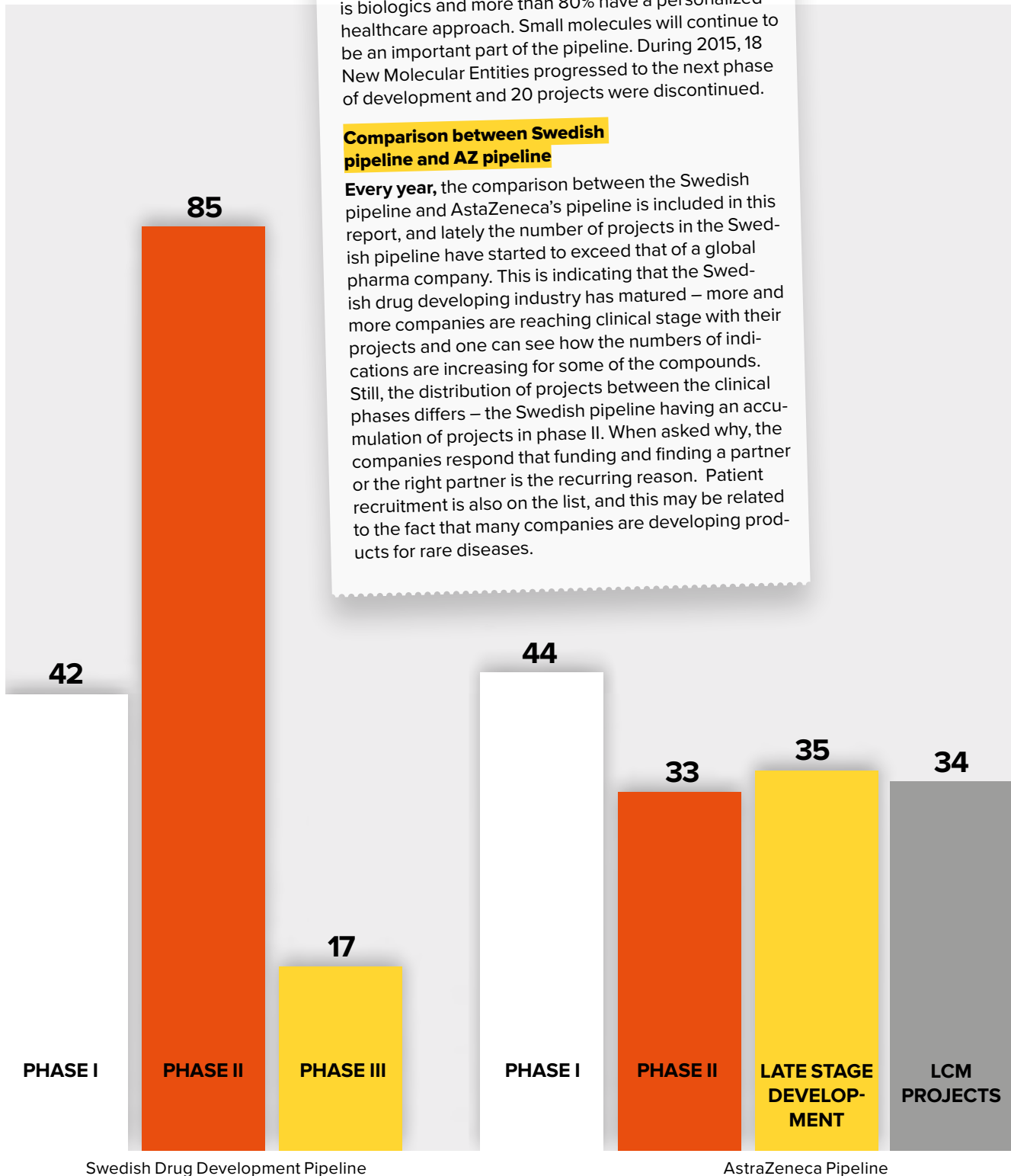
Globally AstraZeneca employs 61,500 people and focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The company also is selectively active in the areas of autoimmunity, neuroscience and infection. In 2015, AstraZeneca invested 5.6 bn USD (47 bn SEK) in R&D. This represents 21.4 of the 2015 revenue, and means that the company invests almost 130 mSEK in research every day.

ASTRAZENECA'S DRUG DEVELOPMENT PIPELINE

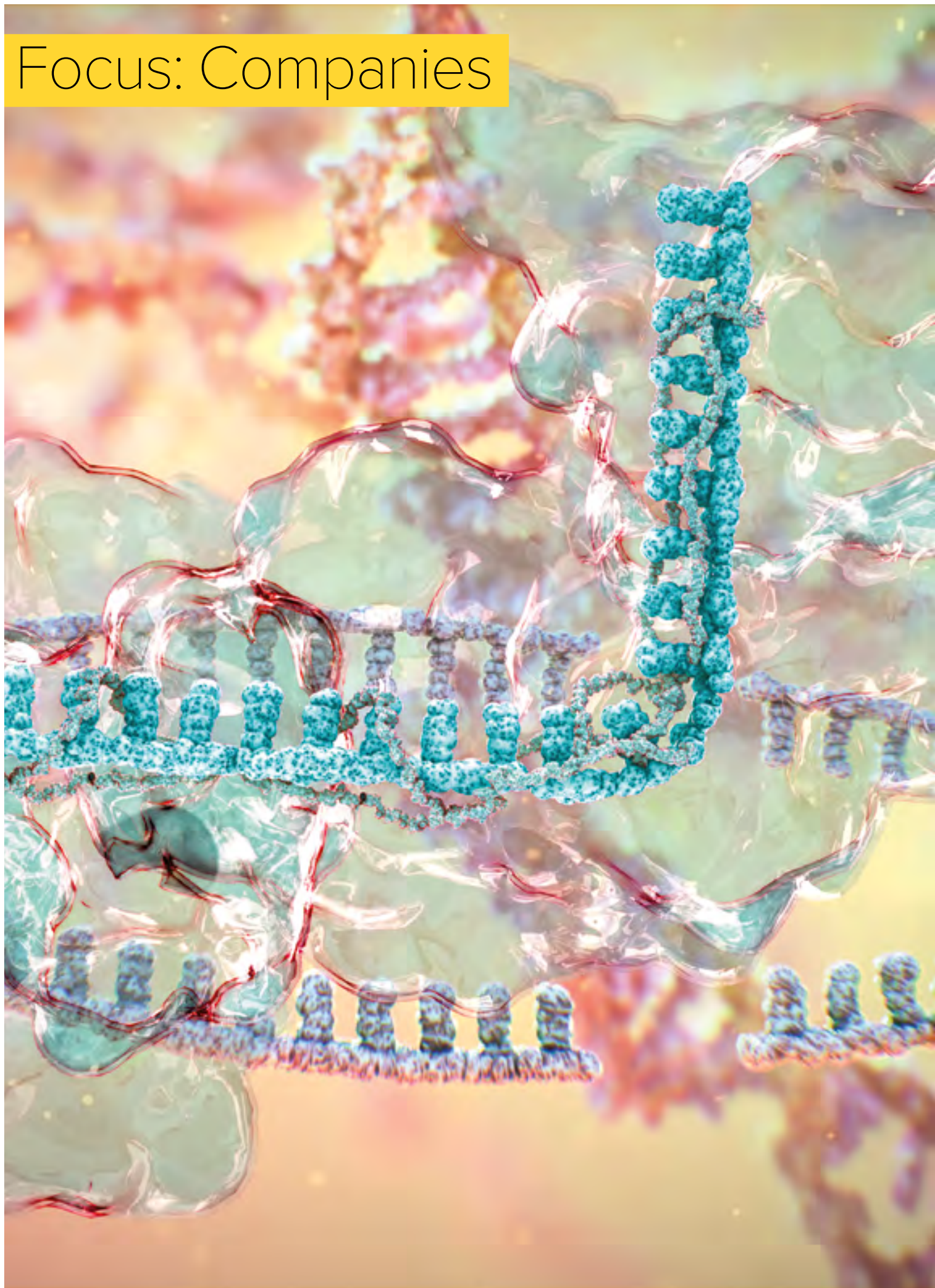
Globally, AstraZeneca reported a pipeline of 146 projects, of which 125 are in the clinical phase of development. This is an increase of 7 projects in clinical development, compared to last year when 118 projects were reported. Of the 125 projects in clinical development, 35 were in late-stage, either in phase III/pivotal Phase II studies or under regulatory review. Most projects are within AstraZeneca's three strategic therapeutic areas; Oncology, Cardiovascular & Metabolic Diseases and Respiratory. About half of the pipeline is biologics and more than 80% have a personalized healthcare approach. Small molecules will continue to be an important part of the pipeline. During 2015, 18 New Molecular Entities progressed to the next phase of development and 20 projects were discontinued.

Comparison between Swedish pipeline and AZ pipeline

Every year, the comparison between the Swedish pipeline and AstraZeneca's pipeline is included in this report, and lately the number of projects in the Swedish pipeline have started to exceed that of a global pharma company. This is indicating that the Swedish drug developing industry has matured – more and more companies are reaching clinical stage with their projects and one can see how the numbers of indications are increasing for some of the compounds. Still, the distribution of projects between the clinical phases differs – the Swedish pipeline having an accumulation of projects in phase II. When asked why, the companies respond that funding and finding a partner or the right partner is the recurring reason. Patient recruitment is also on the list, and this may be related to the fact that many companies are developing products for rare diseases.



Focus: Companies

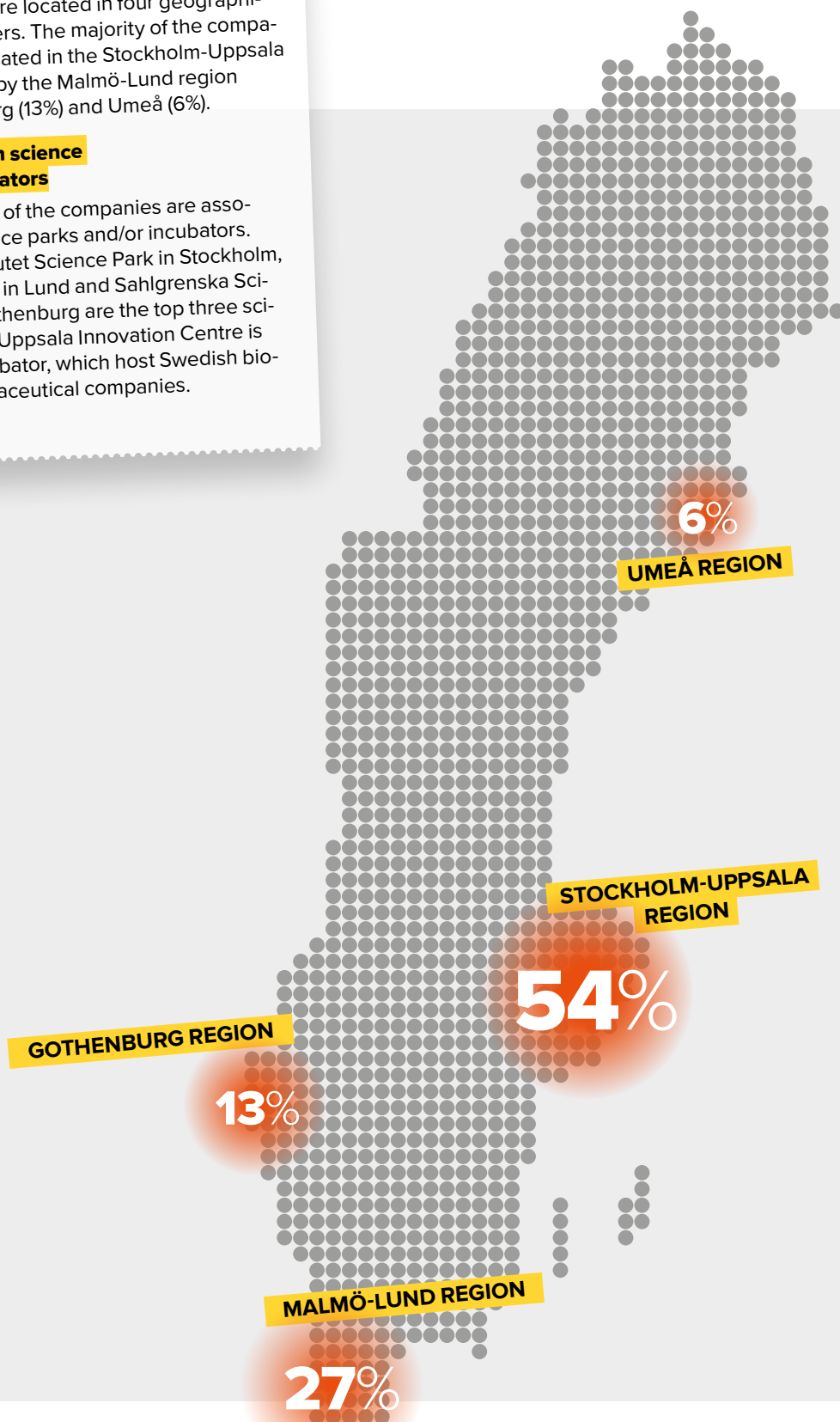


SWEDISH HOT BEDS FOR DRUG DISCOVERY AND DEVELOPMENT

The companies are located in four geographical regional centers. The majority of the companies (54%) are located in the Stockholm-Uppsala region, followed by the Malmö-Lund region (27%), Gothenburg (13%) and Umeå (6%).

Association with science parks and incubators

Slightly over half of the companies are associated with science parks and/or incubators. Karolinska Institutet Science Park in Stockholm, Medicon Village in Lund and Sahlgrenska Science Park in Gothenburg are the top three science parks and Uppsala Innovation Centre is the leading incubator, which host Swedish biotech and pharmaceutical companies.



Source: web-based survey, public databases, company webpages and company interviews.
Location was retrieved from allabolag.se, based on company information from December 2015.

MANY MICRO-SIZED COMPANIES

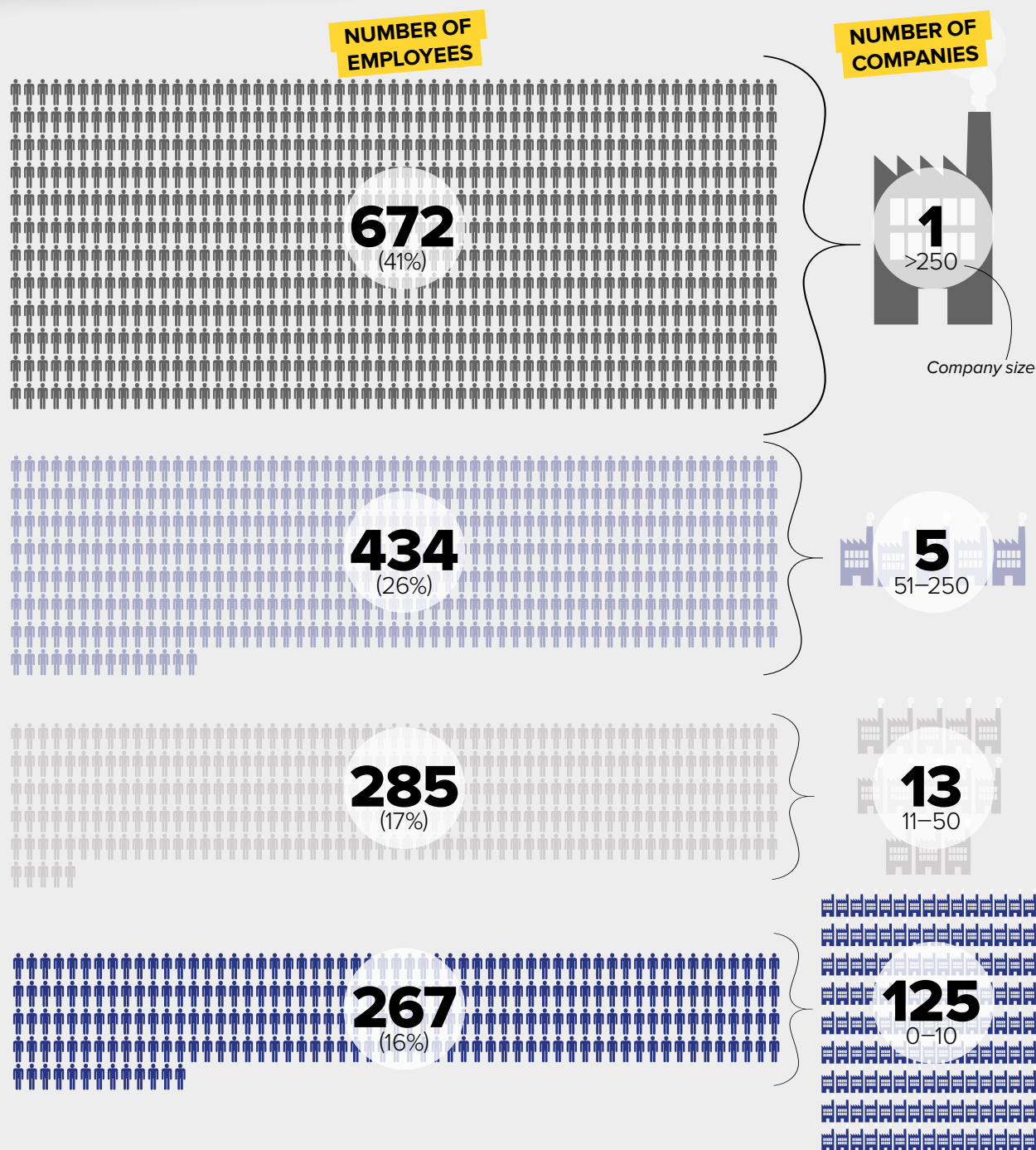
A total of **144 Swedish biotech** and pharmaceutical companies have been identified to be actively working with drug development. Together, the companies in this analysis had more than 1600 employees on their payrolls in 2015, an increase by more than 100 FTE from last year. Swedish Orphan Biovitrum, with 672 employees, is currently the largest research company in Sweden, based on number of employees.

All but one company are so called small or medium-sized enterprises (SME) with up to 250 employees. Of these, five are medium-sized and include Active Biotech,

Karo Pharma, Medivir, Oasmia Pharmaceutical and Orexo with the remaining 138 companies being classified as small-sized employing 552 persons in total. 125 of those are so called micro-sized (0–10 FTE).

Virtual companies

Many of the small-sized companies are so-called “virtual companies”, meaning that they have few employees in-house and a significant part of their R&D allocated to external consultants and specialized service providers.



RECENT PATENTING ACTIVITIES

Patents are essential for the long-term value creation of pharmaceutical drugs in development and the number of patents and patent applications is one of several indications of the innovative climate within a company and signals the potential for future growth.

To get an understanding of the patenting activity for the 144 companies included in this year's report, information was collected on patent publications published from January 2016 to November 2016. Of the 144 companies, 126 were found in the database and 47 of these companies

had one or more published patents during the time period, in total 67 patent publications. Two-thirds of the patent publications originate from micro-sized companies, which make up the vast majority of Swedish companies currently engaged in drug development.

Note: The information and analysis is a contribution from bulb Intelligence. The source data is the information present in the Cortellis database as of November 2016. "Patent publications" include both applications and approved patents.

Top 10 list of largest companies by number of employees

COMPANY	FTE 2015 (FTE 2014)	HEAD OFFICE	THERAPEUTIC AREA	OWNER	FOUNDED	TURNOVER 2015 (TSEK) (TURNOVER 2014)
Swedish Orphan Biovitrum	672 (589)	Stockholm	Rare diseases: inflammation, genetics & metabolism.	Public	1939	3 242 650 (2 646 873)
Medivir	134 (141)	Stockholm	Infectious diseases (Hepatitis C)	Public	1987	675 509 (1 782 212)
Orexo	98 (111)	Uppsala	Opioid dependence, pain, insomnia	Public	1994	677 907 (608 876)
Oasmia Pharmaceutical	98 (74)	Uppsala	Oncology	Public	1988	19 088 (33 978)
Karo Pharma	72 (39)	Stockholm	Nuclear receptors: neuropsychiatry, inflammation, autoimmune diseases and oncology.	Public	1987	69 095 (30 152)
Active Biotech	55 (58)	Lund	Immunology: multiple sclerosis and oncology.	Public	1983	16 275 (10 399)
Camurus	44 (38)	Lund	Oncology, endocrinology, pain, metabolic disease and opioid dependence	Public	2004	154 856 (210 463)
BioInvent International	40 (38)	Lund	Oncology	Public	1997	17 182 (50 468)
Moberg Pharma	30 (18)	Stockholm	Skin diseases	Public	2006	292 275 (205 971)
Affibody	24 (21)	Stockholm	Alzheimer's disease, autoimmune diseases, and psoriasis	Public	2004	90 003 (57 623)

Source: The company information was retrieved from allabolag.se, based on reported numbers from December 2015. Companies founded in 2016, are not included in the analysis, and will be listed in next year's report.

Ten new companies, registered in 2015

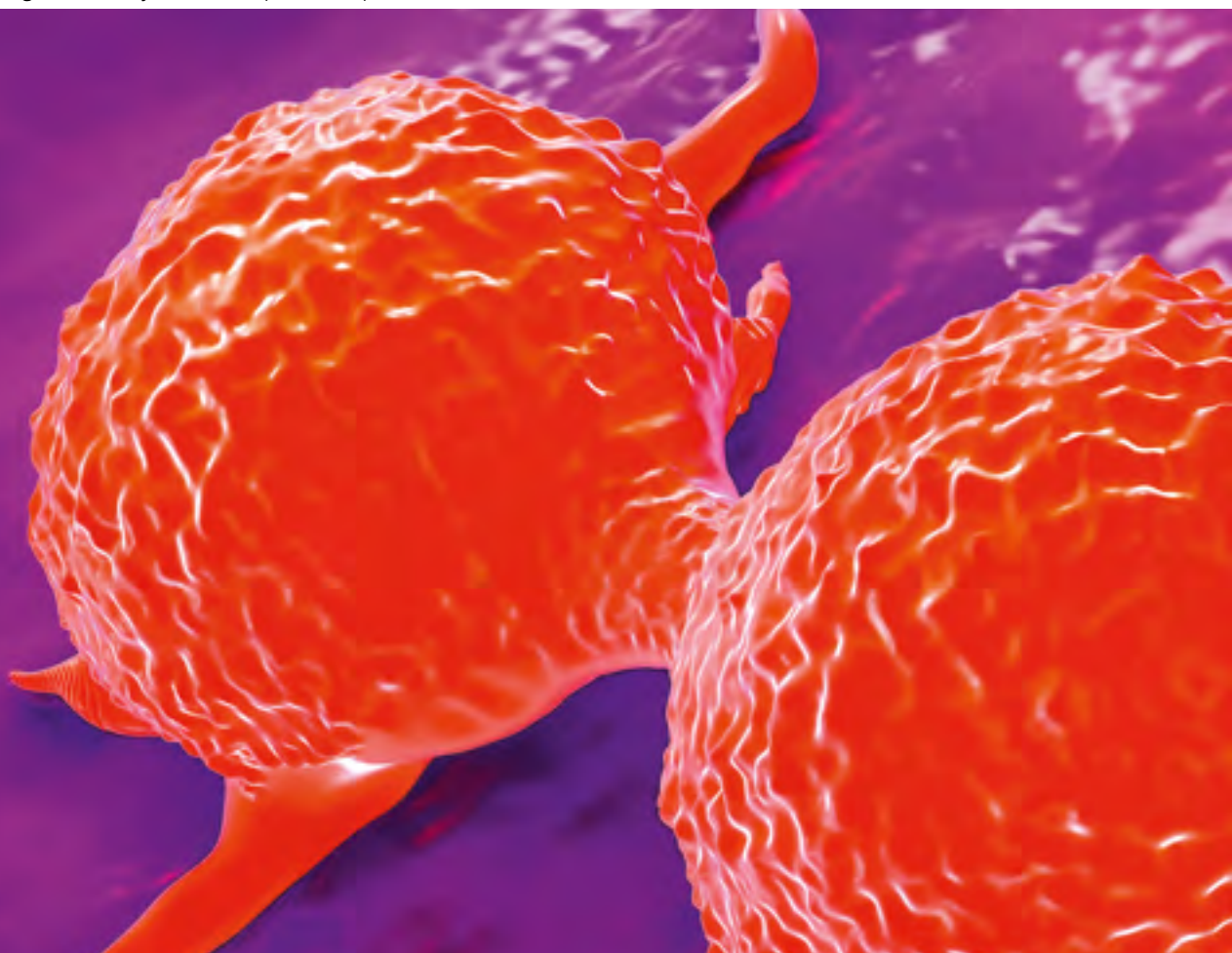
COMPANY	DESCRIPTION
BTB Pharma	A relatively new actor in the biopharmaceutical industry and is a developer of a revolutionary biomedical platform for the treatment of autoimmune disease.
Cyxone	Develop cyclotide drugs for autoimmune and other diseases.
Emeriti Bio	A privately held sister company to Emeriti Pharma AB. The focus is on novel treatment options for heavy menstrual bleeding.
Genagon Therapeutics	Develops a new, unique method for treatment of cancer. Genagon originates from research conducted at Uppsala University and Karolinska Institutet and develops biologics, such as antibodies, against inflammation and cancer.
Inorbit Therapeutics	A drug discovery company which applies a novel chemotype to resurrect small molecule drugs with proven human efficacy, but which failed in late stage development, or the marketplace, due to Drug-Induced Liver Injury (DILI).
Merozyne Therapeutics	Develops a pharmaceutical treatment against laminin alpha2 chain-deficient congenital muscular dystrophy (MDC1A) by exploiting the research conducted at Lund University.
Metynex Pharmaceuticals	A new company committed to the development of pharmaceuticals in the cardiometabolic area. A new principle for treatment of type II diabetes is under development.
Oblique Therapeutics	Develops a new type of antibody-based pharmaceutical against malignant tumor diseases.
RhoVac	Conducts research and development of new therapeutic cancer vaccines.
Stayble Therapeutics	Is developing a minimally invasive injection-based treatment against chronic low back pain triggered by degenerative changes in the disc.

Source: Registration year was retrieved from allabolag.se.

IPOs in 2015

COMPANY	MARKET	DESCRIPTION
Alzinova	Aktietorget	Engaged in the discovery and development of therapeutics for the treatment of Alzheimer's disease.
Aptahem	Aktietorget	Develops drug candidates for the treatment and prevention of diseases caused by blockages in blood vessels as the result of blood clots.
Camurus	Nasdaq Stockholm	Develops and commercializes innovative specialty medicines against serious and chronic disease.
Cantargia	First North	Specializes in antibody-based cancer treatment.
CombiGene	Aktietorget	Has developed a method shown to suppress epileptic seizures in pre-clinical studies.
Double Bond Pharmaceutical International	Aktietorget	Develops and commercializes innovative first-in-class approaches for treatment of cancers, infections, autoimmune diseases and other life-threatening disorders.
Hamlet Pharma	Aktietorget	Works with a new concept of cancer therapy using natural and biological substances.
Idogen	Aktietorget	Develops tolerogenic vaccines which reprogram the immune system.
Karessa Pharma Holding	First North	Develops and commercializes innovative products with clear competitive advantages in the therapeutic area of erectile dysfunction.
Klaria Pharma Holding	First North	Develops innovative, fast-acting medicinal products with clear competitive benefits in the therapeutic fields of migraine and cancer-related pain.
Toleranzia	Aktietorget	Has developed a platform technology for treatment of autoimmune diseases.
Vicore Pharma Holding	First North	Develops new molecules with agonistic action to the AT2 receptor into successful clinical drug entities.

Source: Data on IPOs for 2015 was retrieved from nyemissioner.se and company webpages.



Companies A–Z

A1M Pharma

Abera Bioscience

Active Biotech

AcuCort

AddBIO

Adenovir Pharma

Affibody

Akinion Pharmaceuticals

Albireo

Alligator Bioscience

AlzeCure Foundation

Alzinova

Anamar

Annexin Pharmaceuticals

Apodemus

Apoglyx

Aprea

Aptahem

Asarina Pharma

Athera Biotechnologies

Atrogi

Axcentua Pharmaceuticals

Axelar

Beactica

Betagenon

BioArctic

Biocrine

Biognos

Biolnvent International

Bioimics

BTB Pharma

Camurus

Canimguide Therapeutics

Canqura Oncology

Cantargia

Cellprotect Nordic Pharmaceuticals

Cereno Scientific

ClanoTech

CombiGene

Corline Biomedical

Cyxone

DanPET

Dextech Medical

Diamyd Medical

Dicotyledon

Dilafor

Double Bond Pharmaceutical International

Duttal

Ectin Research

Edvinco

Eirium AB

Elastomics

Emeriti Bio

Emeriti Pharma

Emplicure

Empros Pharma

Eribis Pharmaceuticals

Eurocine Vaccines

Follicum

Gabather

Galecto Biotech

Genagon Therapeutics

Glactone Pharma

Glionova

Glucox Biotech

Grespo

Hamlet Pharma

Hansa Medical

Helicure

Idogen

Immun System I.M.S.

ImmuneBiotech

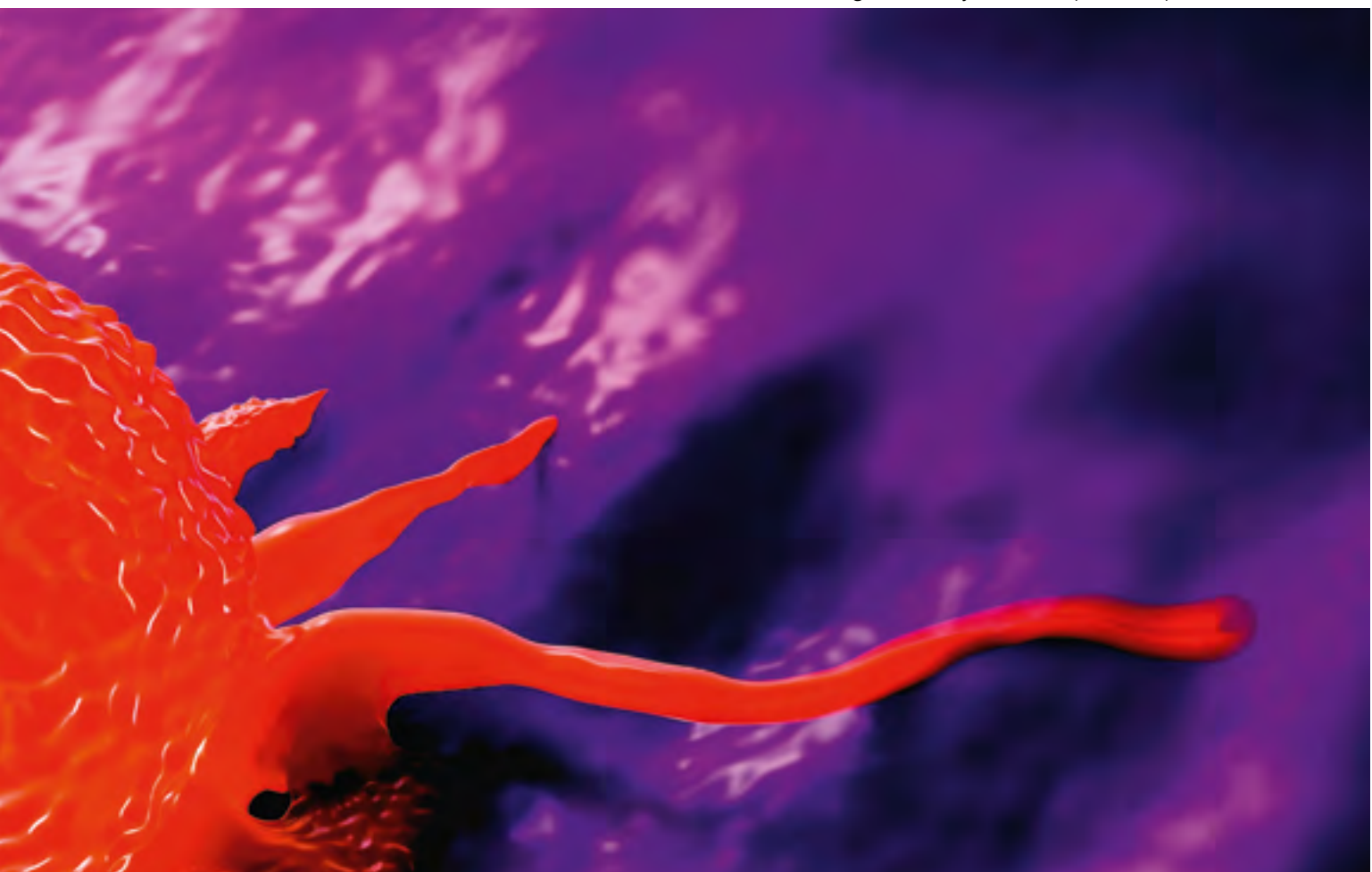
Immuneed

Immunicum

InDex Pharmaceuticals

Infant Bacterial Therapeutics

Inorbit Therapeutics



Companies A–Z

Integrative Research Laboratories

Sweden

IsletOne

Isofol Medical

iCell Science

in2cure

Kancera

Karessa Pharma

Karo Pharma

Klaria Pharma

LIDDS

Lipidor

Lipigon Pharmaceuticals

Lipum

Lokon

Medivir

Merozyne Therapeutics

Metynex

Moberg Pharma

Modus Therapeutics

Molecules of Man

NeuroVive Pharmaceutical

Noviga Research

Oasmia Pharmaceutical

Oblique Therapeutics

Omnia Healer

Oncopeptides

Oncorena

Orexo

OxThera

OxyPharma

Parkcell

Peptonic Medical

Pharmalink

Pharmalundensis

Pharmanest

PharmNovo

Pila Pharma

PledPharma

Promore Pharma

ProNoxis

QuiaPEG Pharmaceuticals

Quretech Bio

Red Glead Discovery

Redwood Pharma

Respiratorius

RhoVac

RSPR Pharma

Scandinavian Biopharma

Sixera Pharma

Spago Nanomedical

Sprint Bioscience

Stayble therapeutics

Swecure

Swedish Orphan Biovitrum

Synphora

TikoMed

Toleranzia

Trophea

Umecrine

Umecrine Cognition

Vicore Pharma

Vivolux

Wilson Therapeutics

WntResearch

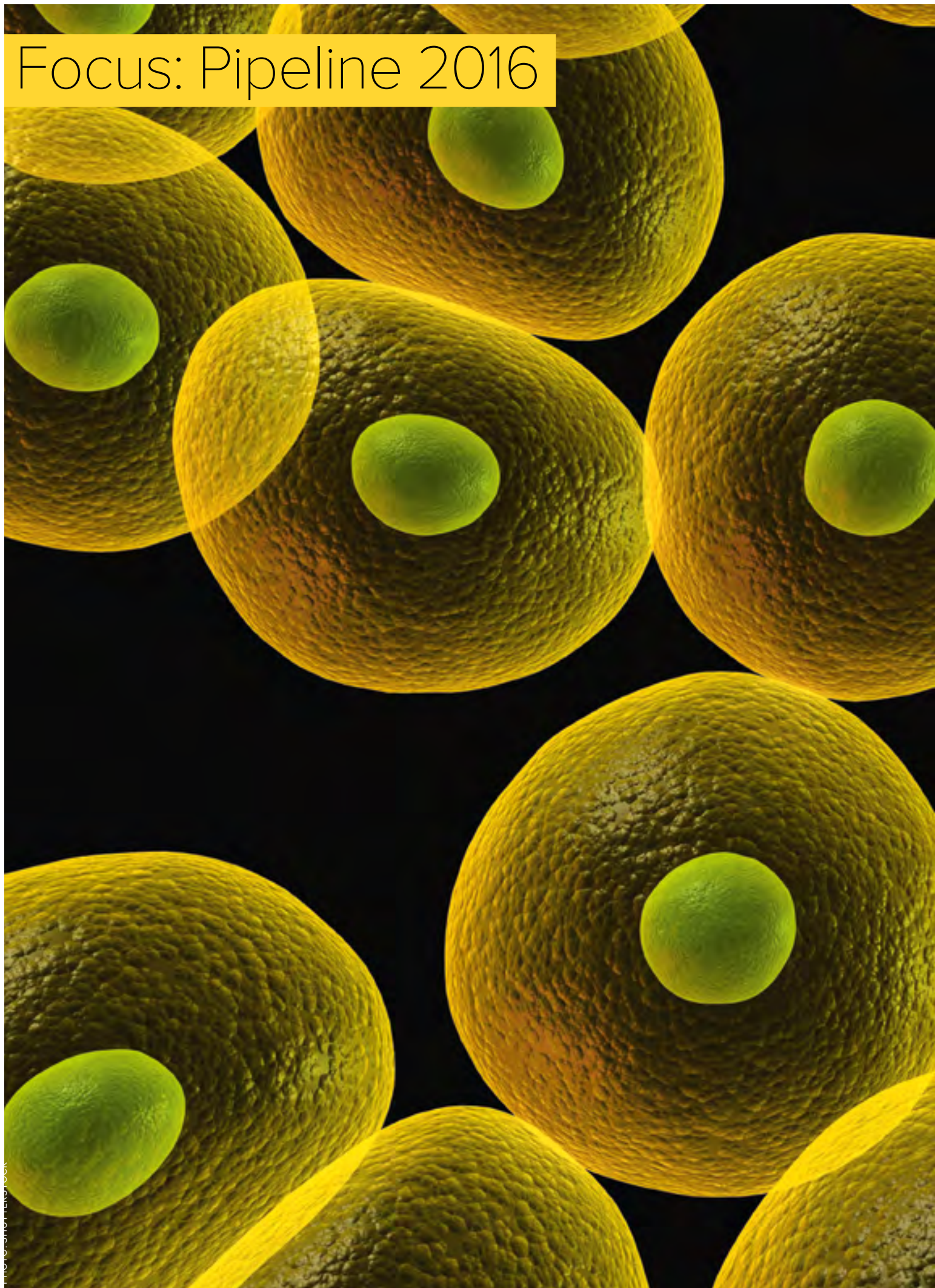
Xbrane

Xintela

Xspray Microparticles

List of 144 companies that actively develop pharmaceutical drugs in Sweden.

Focus: Pipeline 2016



Pipeline 2016

COMPANY	COMPOUND	INDICATION	THERA- PEUTIC AREA	PART- NERING STATUS	PHASE
A1M Pharma	A1M	Preeclampsia	Obstetrics		●●
A1M Pharma	A1M	Kidney protection	Oncology		●
Abera Bioscience	OMV Vaccine	Acinetobacter Baumannii infection	Infection	Partner	●
Abera Bioscience	OMV Vaccine	Chlamydia infection	Infection	Available	●
Abera Bioscience	OMV Vaccine	Pneumococcal disease	Infection	Available	●
Abera Bioscience	OMV Vaccine	Tuberculosis	Infection	Available	●
Abera Bioscience	Cancer Vac	Undisclosed	Undisclosed	Available	●
Active Biotech	Laquinimod	Relapsing-remitting MS	Immunology	Partner	●●●●●●●●
Active Biotech	Laquinimod	Relapsing-remitting MS	Immunology	Partner	●●●●●●●●
Active Biotech	Laquinimod	Relapsing-remitting MS	Immunology	Partner	●●●●●●●●
Active Biotech	ANYARA	Renal cell cancer*	Immuno- Oncology		●●●●●●●●
Active Biotech	Tasquinimod	Prostate cancer	Oncology	Available	●●●●●●●●
Active Biotech	Laquinimod	Huntington's disease*	CNS	Partner	●●●●●●●●
Active Biotech	Laquinimod	Primary progressive MS	Immunology	Partner	●●●●●●●●
Active Biotech	Paquinimod	Systemic Sclerosis	Immunology	Available	●●●●●●●●
Active Biotech	SILC	Cancer	Oncology	Available	●●
Active Biotech	Tasquinimod	Multiple myeloma	Oncology	Available	●●
Active Biotech	Laquinimod	Crohn's Disease	Gastro-Intes- tinal	Partner	●●●●●
Active Biotech	Laquinimod	Lupus	Immunology	Partner	●●●●●
Active Biotech	ANYARA	Non-small cell lung carcinoma	Immuno- Oncology	Partner	●●●●
AcuCort	DexaODF	Allergic reactions	Immunology	Available	●●●●●●●●
AcuCort	DexaODF	Chemotherapy-induced nausea	Other	Available	●●●●●●●●
AddBIO	Undisclosed	Bone diseases	Other		●
Adenovir Pharma	APD-514	Adenoviral conjunctivitis	Infection	Available	●●
Adenovir Pharma	APD-209	Adenoviral conjunctivitis	Infection	Available	●●●●●
Affibody	ABY-057	Alzheimer's disease	CNS		●●
Affibody	ABY-039	Antibody mediated autoimmune diseases	Immunology		●●
Affibody	ABY-035	Psoriasis	Dermatology		●●●●
Akinion Pharmaceuticals	Kinase Inhibitors	Tumors	Oncology		●
Albireo	Elobixibat	Chronic constipation	Gastro- Intestinal	Available	●●●●●●●●
Albireo	A3384	Bile Acid Malabsorption	Gastro- Intestinal	Available	●●●●●●●●
Albireo	A4250	Pediatric cholestatic liver diseases*	Gastro- Intestinal	No answer	●●●●●●●●
Albireo	A4250	Progressive Familial Intrahepatic Cholestasis*	Gastro- Intestinal	No answer	●●●●●●●●

● Preclinical No CDN ● Preclinical CDN ● Phase I ● Phase IIa ● Phase IIb ● Phase III

* Orphan indication

Pipeline 2016

COMPANY	COMPOUND	INDICATION	THERA- PEUTIC AREA	PART- NERING STATUS	PHASE
Albireo	Elobixibat	Irritable Bowel Syndrome	Gastro- Intestinal	Available	●●●●●●
Albireo	Local PPAR agonist	Inflammatory Bowel diseases	Gastro- Intestinal	Available	●●
Albireo	Bile Acid Modulator	Nonalcoholic steatohepatitis	Gastro- Intestinal	No answer	●
Alligator Bioscience	ATOR-1015	Solid tumor	Immuno- Oncology	Available	●●
Alligator Bioscience	ATOR-1016	Solid tumor	Immuno- Oncology	Available	●
Alligator Bioscience	ADC-1013	Hematological disease	Immuno- Oncology	Out-licensed	●●●●
Alligator Bioscience	ADC-1013	Solid tumor	Immuno- Oncology	Out-licensed	●●●●
Alzecure Discovery	N/A	Alzheimer's disease	CNS	Available	●●
Alzecure Discovery	N/A	Alzheimer's disease	CNS	Available	●
Alzinova	ALZ-101	Alzheimer's disease	CNS	Available	●●
AnaMar	5-HT platform	Fibrosis		Available	●
Annexin Pharmaceuticals	Annexin A5	Cardiovascular diseases	Cardio- vascular		●
Annexin Pharmaceuticals	Annexin A5	Viral Hemoragic Fevers	Infection		●
Apodemus	Pleconaril	Alzheimer's disease	CNS	No answer	●●●●●●
Apoglyx	AQP9	Type-2 diabetes	Diabetic/ Metabolism		●
Aprea	APR-246	Additional indications	Oncology		●●
Aprea	APR-246	Esophageal Cancer*	Oncology		●●●●
Aprea	APR-246	High Grade Serous Ovarian Cancer*	Oncology		●●●●
Aprea	APR-246	Myelodysplastic Syndrome*	Oncology		●●●●
Aprea	APR-246	High Grade Serous Ovarian Cancer*	Oncology		●●●●●●
Aptahem	Apta-1	Blood clotting	Cardio- vascular	Available	●●
Asarina Pharma	UC2016	Premenstrual Dysphoric Disorder	Psychiatry		●●
Asarina Pharma	UC2018	Not decided yet	Undisclosed		●
Asarina Pharma	Sepranolone	Premenstrual Dysphoric Disorder	Psychiatry		●●●●●●
Athera Biotechnologies	PC-mAb	Secondary prevention in PAD patients	Cardio- vascular	Available	●●●●
Athera Biotechnologies	PC-mAb	AV access dysfunction in dialysis patients*	Cardio- vascular	Available	●●
Athera Biotechnologies	PC-mAb	Heart failure	Cardio- vascular	Available	●●
Athera Biotechnologies	PC-mAb	Secondary prevention after CABG intervention	Cardio- vascular	Available	●●

● Preclinical No CDN ● Preclinical CDN ● Phase I ● Phase IIa ● Phase IIb ● Phase III

* Orphan indication

COMPANY	COMPOUND	INDICATION	THERA- PEUTIC AREA	PART- NERING STATUS	PHASE
Athera Biotechnologies	PC-mAb	Rheumatoid Arthritis	Rheumatology	Available	●●
Athera Biotechnologies	PC-mAb 2	Several	Cardiovas- cular	Available	●●
Atrogi	N/A	Diabetes	Diabetic/ Metabolism		●
Atrogi	N/A	Diabetes	Diabetic/ Metabolism		●
Axcentua Pharmaceuticals	AXP107-11	Locally advanced or metastatic pancreatic cancer*	Oncology		●●●●
Axelar	AXL-1717	Glioblastoma	Oncology	Available	●●●●
Axelar	AXL-1717	Non-small cell lung carcinoma	Oncology	Available	●●●●
Beactica	Undisclosed	Undisclosed*	Undisclosed	Available	●
Beactica	Undisclosed	Undisclosed*	Undisclosed	Partner	●
Betagenon	O304	Cardiovascular disorders	Cardiovas- cular	Available	●●●●
Betagenon	O304	Diabetes	Diabetic/ Metabolism	Available	●●●●
Betagenon	O304	Metabolic disorders	Diabetic/ Metabolism	Available	●●●●
BioArctic	BAN2401	Alzheimer's disease	CNS		●●●●●
BioArctic	SC0806	Spinal Cord Injury*	CNS		●●●
BioArctic	BAN0805	Parkinson's disease	CNS		●●
BioArctic	BAN2502	Alzheimer's disease	CNS		●●
Biocrine	apoCIII	Diabetes	Diabetic/ Metabolism		●
Biocrine	Calcium channels	Diabetes	Diabetic/ Metabolism		●
Biocrine	Imidazoline BL11282	Diabetes	Diabetic/ Metabolism		●
Biocrine	Insulin receptor isoforms	Diabetes	Diabetic/ Metabolism		●
Biocrine	Somatostatin receptors	Diabetes	Diabetic/ Metabolism		●
Biognos	N/A	Cancer	Oncology		●
Biognos	N/A	Cancer	Oncology		●
Biognos	N/A	Winter-vomiting disease.	Infection		●
Bioimics	Ribozyme inhib- itors	Healthcare Associated Infections	Infection		●
Biolnvent International	OX40 and 4-1BB	Cancer	Immuno- Oncology		●
Biolnvent International	Tumour-associated myeloid cells	Cancer	Immuno- Oncology		●
Biolnvent International	BI-1206	Chronic lymphatic leukemia*	Immuno- Oncology		●●●●
Biolnvent International	BI-1206	Non Hodgkins lymphoma*	Immuno- Oncology		●●●●

Source: web-based survey, public databases, company webpages and company interviews. Notice: The information and data contained in this document are believed to be correct. However, we are not liable for any errors or misprint that might occur.

Pipeline 2016

COMPANY	COMPOUND	INDICATION	THERAPEUTIC AREA	PARTNERING STATUS	PHASE
Biolinvent International	BI-505	Multiple Myeloma*	Immuno-Oncology		●●●●●
Biolinvent International	TB-403	Medulloblastoma*	Immuno-Oncology		●●●●●
BTB Pharma	BTB 001	Multiple Sclerosis	Inflammation		●●
BTB Pharma	BTB 002	Type-1 diabetes	Diabetic/Metabolism		●
Camurus	CAM 2038 (q1w)	Chronic pain	Pain	Partner	●●●●●●●
Camurus	CAM 2038 (q4w)	Chronic pain	Pain	Partner	●●●●●●●
Camurus	CAM 2038 (q1w)	Opioid dependence	Psychiatry	Partner	●●●●●●●
Camurus	CAM 2038 (q4w)	Opioid dependence	Psychiatry	Partner	●●●●●●●
Camurus	CAM2029	Acromegaly*	Endocrinology	Partner	●●●●●●●
Camurus	CAM2029	Neuroendocrine tumors*	Oncology	Partner	●●●●●●●
Camurus	CAM2032	Prostate cancer	Oncology		●●●●●●●
Camurus	CAM2047	Chemotherapy-Induced Nausea	Other		●●●
Camurus	CAM2048	Post surgery pain	Pain	Partner	●●●
Camurus	CAM2058	Post surgery pain	Pain	Partner	●●●
Camurus	CAM4071	Undisclosed indication	Undisclosed	Partner	●●●
Canimguide Therapeutics	P28R	Oncology	Oncology		●
Cantargia	CAN04	Non-small cell lung carcinoma	Immuno-Oncology	Available	●●
Cantargia	CAN04	Pancreatic cancer	Immuno-Oncology	Available	●
CellProtect Nordic Pharmaceuticals	CellProtect	Multiple Myeloma*	Immuno-Oncology	Available	●●●
Cereno Scientific	CS1	Blood clotting	Hematology		●●
Clanotech	CLT-28643	Glaucoma*	Ophthalmology		●●
Clanotech	CLT-28643	Age related Macular Degeneration	Ophthalmology		●
CombiGene	CG01	Epilepsy	CNS		●●
Corline Biomedical	Cytoparin™	Cell Therapy/Diabetes Type 1	Diabetic/Metabolism		●●●
Corline Biomedical	Renaparin™	Kidney Transplantation*	Transplantation		●●
Cyxone	T20K	Multiple Sclerosis	CNS		●●
DanPET	N/A	Corticobasal degeneration	CNS	Partner	●●
DanPET	N/A	Tardative dyskinesia	CNS	Partner	●●
DanPET	N/A	Diagnosis of vulnerable plaque	Cardiovascular	Available	●●
Dextech Medical	SomaDex	Acromegaly	Endocrinology	Available	●●●●●●●
Dextech Medical	OsteoDex	Metastatic Castration Resistant Prostate Cancer	Oncology	Out-licensed	●●●●●●●
Dextech Medical	SomaDex	Neuroendocrine tumors	Oncology	Available	●●●●●●●

● Preclinical No CDN ● Preclinical CDN ● Phase I ● Phase IIa ● Phase IIb ● Phase III

* Orphan indication

COMPANY	COMPOUND	INDICATION	THERA- PEUTIC AREA	PART- NERING STATUS	PHASE
Dextech Medical	SomaDex	Palliative treatment of prostate cancer	Oncology	Available	●●●●●●
Dextech Medical	CatDex	Oral antiseptic	Infection	Partner	●●
Dextech Medical	CatDex	Superficial bladder cancer	Oncology	Partner	●●
Diamyd Medical	GABA	Type 1 diabetes	Diabetic/ Metabolism		●●●●
Diamyd Medical	GAD	Autoimmune diabetes	Diabetic/ Metabolism		●●●●●●
Dicotyledon	Libiguins	Sexual dysfunction	Gynecology		●
Dilafor	Tafoxiparin	Dystocia/Protracted Labor	Obstetrics		●●●●●●
Double Bond Pharmaceutical	SA-033	Hepatoblastoma*	Oncology	Available	●●
Double Bond Pharmaceutical	SA-033	Hepatocellular carcinoma*	Oncology	Available	●●
Double Bond Pharmaceutical	SA-033	Secondary cancers in liver	Oncology	Available	●●
Double Bond Pharmaceutical	SA-083	Lung cancer	Oncology	Available	●●
Double Bond Pharmaceutical	Temodex	Operable primary brain tumors*	Oncology	Available	●●
Double Bond Pharmaceutical	Temodex	Operable secondary brain tumors	Oncology	Available	●●
Double Bond Pharmaceutical	SA-042	Bacterial pneumonia	Pulmonary	Available	●●
Duttal	N/A	Anti-obesity lipid-based drug	Diabetic/ Metabolism		●
Ectin Research	MFA-370	Bladder cancer	Oncology	Available	●●
Edvince	N/A	Stroke	Cardiovas- cular		●●
Edvince	N/A	Stroke	Cardiovas- cular		●
Edvince	N/A	Stroke	Cardiovas- cular		●
Eirium	Antiviral therapies	Treatment of immunocompromised patients	Immunology		●
Elastomics	MMP9	Islet transplantation	Diabetic/ Metabolism		●●
Elastomics	MMP9	Fibrosis	Pulmonary		●●
Elastomics	MMP9	Dupuytren's Disease	Rheumatology		●●
Emeriti Bio	N/A	Heavy menstrual bleeding	Gynecology		●
Emeriti Pharma	EP0003	Rosacea	Dermatology		●●●●
Emeriti Pharma	EP0003	Melasma	Dermatology		●●
Emeriti Pharma	EP0003	Plaque psoriasis	Dermatology		●●
Emplicure	N/A	Moderate to severe chronic pain	Pain		●●
Emplicure	N/A	Moderate to severe chronic pain	Pain		●●
Emplicure	N/A	Premedication in children ahead of painful procedures	Pain		●●

Source: web-based survey, public databases, company webpages and company interviews. Notice: The information and data contained in this document are believed to be correct. However, we are not liable for any errors or misprint that might occur.

Pipeline 2016

COMPANY	COMPOUND	INDICATION	THERA- PEUTIC AREA	PART- NERING STATUS	PHASE
Empros Pharma	Combination of orlistat and acarbose	Obesity	Diabetic/ Metabolism	Available	●●●●●
Empros Pharma	Combination of orlistat and acarbose	Type 2 diabetes	Diabetic/ Metabolism	Available	●●●●●
Empros Pharma	Combination of orlistat and acarbose	NASH	Gastro-Intes- tinal	Available	●●●●●
Eribis Pharmaceuticals	EP94	Acute Myocardial Infarction	Cardiovas- cular		●●
Eurocine Vaccines	Influenza vaccine	Pandemic influenza prevention	Infection	Available	●●
Eurocine Vaccines	Endocrine, nasal vaccine delivery	Diseases transmitted via upper airways	Infection	Available	●●●●●
Eurocine Vaccines	Influenza vaccine	Seasonal influenza prevention	Infection	Available	●●●●●
Follicum	FOL-005	Hypertrichosis	Dermatology	Available	●●●●●
Follicum	FOL-005	Unwanted hair growth	Dermatology	Available	●●●●●
Follicum	FOL-005	Hirsutism	Endocrinology	Available	●●●●●
Follitech	N/A	Premature ovarian failure	Obstetrics		●
Gabather	GT-002	Psychosis/Depression	Psychiatry		●●
Galecto Biotech	GB-03	NASH	Gastro-Intes- tinal	Partner	●●
Galecto Biotech	GB-03	Kidney fibrosis	Nephrology	Partner	●●
Galecto Biotech	GB-02	Age-related macular degeneration	Ophthalmology	Available	●●
Galecto Biotech	GB-02	Diabetic retinopathy	Ophthalmology	Available	●●
Galecto Biotech	GB-02	Ocular fibrosis*	Ophthalmology	Available	●●
Galecto Biotech	TD139	Idiopathic pulmonary fibrosis*	Pulmonary	Partner	●●●●●
Genagon Therapeutics	N/A	Increase response rates in immu- no-oncology	Immuno-On- cology		●
Genagon Therapeutics	N/A	Increase response rates in immuno-oncology	Inflammation		●
Glactone Pharma Devel- opment	GPA500	Castration resistant prostate cancer	Immuno-On- cology		●
Glionova	GLN-1001	Glioblastoma	Oncology		●●
Glucox Biotech	N/A	Diabetes complications	Diabetic/ Metabolism	Available	●●
Glucox Biotech	N/A	Diabetes complications	CNS	Available	●●
Grespo	GRE213	MCI	CNS	Available	●●
Hamlet Pharma	HAMLET	Colon cancer	Oncology		●●●●
Hamlet Pharma	HAMLET	Bladder cancer	Oncology		●●●●
Hansa Medical	IdeS	Thrombotic thrombocytopenic purpura*	Cardiovas- cular		●●●●●
Hansa Medical	EndoS	Autoimmune disease	Immunology		●
Hansa Medical	NiceR	Recurring treatment in autoimmune disease	Immunology		●

● Preclinical No CDN ● Preclinical CDN ● Phase I ● Phase IIa ● Phase IIb ● Phase III

* Orphan indication

COMPANY	COMPOUND	INDICATION	THERAPEUTIC AREA	PARTNERING STATUS	PHASE
Hansa Medical	EnzE	Cancer Immunotherapy	Immuno-On-cology		●
Hansa Medical	IdeS	Other kidney transplant indications*	Transplanta-tion		●●●●●
Hansa Medical	IdeS	Kidney transplants in sensitized patients*	Transplanta-tion		●●●●●
Helicure	Vaccine	Gastric cancer	Immuno-On-cology		●●
Helicure	Passive immunotherapy	Gastritis	Gastro-Intes-tinal		●
iCell Science	Tregs with immunophenotype	Transplantation rejection*	Transplanta-tion		●●●●●
iCell Science	Mesenchymal stromal/stem cells	Transplantation rejection*	Transplanta-tion		●●●●●
Idogen	Tolerogenic vaccine	Haemophilia A patients	Immunology		●●
Idogen	Undisclosed	Undisclosed	Immunology		●
ImmuneBiotech	IB001	Irritable Bowel Syndrome*	Gastro-Intes-tinal		●●
ImmuneBiotech	IB002	Clostridium difficile*	Infection		●●
Immuneed	Peptide-based conjugate vaccine		Oncology		●●
Immunicum	INTUVAX	Renal cell carcinoma*	Immuno-Oncology		●●●●●●
Immunicum	INTUVAX	Gastrointestinal stromal tumor *	Immuno-Oncology		●●●●
Immunicum	INTUVAX	Hepatocellular carcinoma*	Immuno-Oncology		●●●●
Immunicum	AdSPTDf35-ade-novirus vector	Cancer	Immuno-Oncology		●
Immunicum	CD70	Cancer	Immuno-Oncology		●
Immunicum	SUBCUVAX	Cancer	Immuno-Oncology		●
Immunsystem I.M.S.	Anti-Pseudomonas IgY	Cystic fibrosis*	Pulmonary		●●●●●●●
in2cure	TCP-25	Wound healing	Dermatology		●●
InDex Pharmaceuticals Holding	Cobitolimod	Ulcerative colitis	Gastro-Intestinal	Available	●●●●●●
InDex Pharmaceuticals Holding	DIMS 9054	Inflammation	Inflammation	Available	●
InDex Pharmaceuticals Holding	DIMS 9059	Inflammation	Inflammation	Available	●
Infant Bacterial Therapeutics	IBP-9414	Prevention of necrotizing enterocolitis*	Gastro-Intestinal	No answer	●●●●●

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Pipeline 2016

COMPANY	COMPOUND	INDICATION	THERA- PEUTIC AREA	PART- NERING STATUS	PHASE
Inorbit Therapeutics	N/A	Type-2 diabetes	Diabetic/ Metabolism		●
Inorbit Therapeutics	N/A	Gout	Inflammation		●
Inorbit Therapeutics	N/A	Nonalcoholic steatohepatitis	Gastro-Intes- tinal		●
Inorbit Therapeutics	N/A	Inflammation/Pain	Pain		●
Integrative Research Laboratories Sweden	IRL752	Parkinson's disease dementia	CNS	Available	●●●
Integrative Research Laboratories Sweden	IRL790	Parkinsons Disease dyskinesias	CNS	Available	●●●
Integrative Research Laboratories Sweden	IRL626	Schizophrenia	Psychiatry	Available	●●
Integrative Research Laboratories Sweden	IRL448	Parkinson's disease	CNS	Available	●
Integrative Research Laboratories Sweden	IRLXXX	Attention disorders	Psychiatry	Available	●
Integrative Research Laboratories Sweden	IRL752	Dementia	Psychiatry	Available	●●●
Integrative Research Laboratories Sweden	IRL790	Parkinsons Disease psychosis	Psychiatry	Available	●●●
IsletOne	Cardiac mesenchymal stromal cells	Heart failure	Cardiovas- cular		●
IsletOne	Human mesenchymal stromal cells	Auto immune diseases	Immunology		●
IsletOne	Human mesenchymal stromal cells	Acute respiratory distress syndrome*	Pulmonary		●●●●
IsletOne	Human mesenchymal stromal cells	Immune rejection after organ transplantation	Transplanta- tion		●●●●
Isofol Medical	Modufolin	Colon cancer	Oncology		●●●●
Isofol Medical	Modufolin	Rectal cancer	Oncology		●●●●
Isofol Medical	Modufolin	Colon cancer (Stage IV)	Oncology		●●●●
Isofol Medical	Modufolin	HDMTX induced toxicity (Osteosarcoma)	Oncology		●●●●
Kancera	ROR inhibitors project	Leukemia and solid tumors	Oncology	Available	●●
Kancera	Project PFKFB3	Solid tumors	Oncology	Available	●●
Kancera	Project HDAC6	Multiple myelom and other cancer diseases	Oncology	Available	●
Kancera	Fractalkine project	Solid tumors and cancer pain	Oncology	Available	●

● Preclinical No CDN ● Preclinical CDN ● Phase I ● Phase IIa ● Phase IIb ● Phase III

* Orphan indication

COMPANY	COMPOUND	INDICATION	THERA- PEUTIC AREA	PART- NERING STATUS	PHASE
Karessa	Sildenafil	Erectile dysfunction	Gynecology		●●
Karessa	Tadalafil	Erectile dysfunction	Gynecology		●●
Karo Pharma	RORgamma	Multiple Sclerosis	CNS	Available	●●
Klaria	KL-00119	Cluster Headache	CNS	Available	●●●
Klaria	KL-00119	Migraine	CNS	Available	●●●
Klaria	KL-00204	Cluster Headache	CNS	Available	●●
Klaria	KL-00204	Migraine	CNS	Available	●●
Klaria	KL-00514	Opiate Overdose	Emergency medicine	Available	●●
Klaria	KL-00406	Breakthrough Cancer Pain	Pain	Available	●●
LIDDS	2- hydroxy-flutamide with Nano-Zolid technology	Localized prostate cancer	Oncology	Other	●●●●●
LIDDS	Docetaxel with NanoZolid technology	Small-cell carcinoma	Oncology	No answer	●●
LIDDS	Docetaxel with NanoZolid technology	Local cancer tumors sensitive to docetaxel	Oncology	No answer	●
Lipidor	Calcipotriol in AKVANO®	Psoriasis	Dermatology	Partner	●●●●●
Lipigon Pharmaceuticals	N/A	Undisclosed	Diabetic/ Metabolism	Partner	●
Lipigon Pharmaceuticals	N/A	Nonalcoholic steatohepatitis	Diabetic/ Metabolism		●
LipUm	Human monoclonal antibody	Inflammatory Bowel Disease	Gastro-Intestinal		●●
LipUm	Human monoclonal antibody	Other Inflammatory Diseases	Inflammation		●●
LipUm	Human monoclonal antibody	Juvenile Idiopathic arthritis*	Rheumatology		●●
Lokon Pharma	LOAd703	Pancreatic cancer*	Immuno-On-cology	Available	●●●●
Lokon Pharma	LOAd703	Solid malignancy	Immuno-On-cology	No answer	●●
Lokon Pharma	LOAd703	Lymphoma*	Immuno-On-cology	No answer	●
Medivir	3DAA FDC	Hepatitis C	Infection		●●●●●
Medivir	MIV-818	Hepatocellular cancer	Oncology		●●
Medivir	MIV-711	Arthritis	Rheumatology		●●●●
Merozyne Therapeutics	N/A	Laminin alpha2 chain-deficient congenital muscular dystrophy	Genetics		●
Metynex Pharmaceuticals	N/A	Type-2 diabetes	Diabetic/ Metabolism		●
Moberg Pharma	MOB-015	Onychomycosis	Infection	Available	●●●●●
Moberg Pharma	BUPI	Pain treatment for Oral mucositis	Pain	Available	●●●●●

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Pipeline 2016

COMPANY	COMPOUND	INDICATION	THERAPEUTIC AREA	PARTNERING STATUS	PHASE
Modus Therapeutics	Sevuparin	Treatment of vaso-occlusive crisis in patients with sickle cell disease*	Hematology	Available	●●●●●●
Modus Therapeutics	Sevuparin	Treatment of early symptoms of VOC in patients with SCD*	Hematology	Available	●●●●●●
Modus Therapeutics	Sevuparin	Treatment of severe malaria*	Infection	Available	●●●●●●
Molecules of man	Human monoclonal	Liver transplantation*	Transplantation		●●
Molecules of man	Human monoclonal	Chronic HCV with virus resistant to oral drugs*	Infection		●
NeuroVive Pharmaceutical	NeuroSTAT	Traumatic Brain Injury*	CNS	Other	●●●●●●
NeuroVive Pharmaceutical	NVP018	NASH (non-alcoholic steatohepatitis)	Gastro-Intestinal	Available	●●
NeuroVive Pharmaceutical	NVP018	Organ protection	Other		●●
NeuroVive Pharmaceutical	NVP015	Genetic mitochondrial diseases*	Genetics	Other	●
Noviga Research	NOV202	Ovarian cancer	Oncology	Available	●●
Oasmia Pharmaceutical	Apealea/Pacical	Metastatic breast cancer	Oncology		●●●●
Oasmia Pharmaceutical	Deocecal	Breast cancer	Oncology		●●●●
Oasmia Pharmaceutical	QAS-19	Various cancers	Oncology		●
Oblique Therapeutics	N/A	Malignant tumor diseases	Oncology	Available	●●
Oblique Therapeutics	N/A	N/A	Diabetic/Metabolism	Partner	●
Oblique Therapeutics	N/A	N/A	Diabetic/Metabolism	Partner	●
Oblique Therapeutics	N/A	N/A	Oncology	Available	●
Oblique Therapeutics	N/A	Inflammation-/Cancer induced pain	Pain	Available	●
Omnio Healer	Plasminogen	Diabetic foot ulcers	Diabetic/Metabolism		●●
Omnio Healer	Plasminogen	Diabetic foot ulcers	Diabetic/Metabolism		●
Omnio Healer	Plasminogen	Infection	Infection		●
Omnio Healer	Plasminogen	Periodontitis	Inflammation		●
Omnio Healer	Plasminogen	Tympanic membrane healing	Otorhino-laryngology		●
Oncopeptides	Melflufen	Multiple myeloma*	Oncology	Available	●●●●●●
Oncopeptides	Melflufen	Acute myeloid leukemia	Oncology		●●
Oncopeptides	Melflufen	Ovarian cancer	Oncology		●●
Oncopeptides	Melflufen	Amyloidosis	Rheumatology		●●

● Preclinical No CDN ● Preclinical CDN ● Phase I ● Phase IIa ● Phase IIb ● Phase III

* Orphan indication

COMPANY	COMPOUND	INDICATION	THERA- PEUTIC AREA	PART- NERING STATUS	PHASE
Oncorena	Orellanine	Metastatic renal clear cell cancer	Oncology	Available	●●
Orexo	OX51	Procedure induced pain	Pain	Available	●●●●●
Orexo	OXCLI	Inflammation	Inflammation	Out-licensed	●●
Orexo	Non-disclosed	Undisclosed	Undisclosed	No answer	●
OxThera	Oxazyme	Enteric and absorptive hyperoxalurias	Endocrinology		●●●
OxThera	OxaBact	Primary Hyperoxaluria*	Endocrinology		●●●●●
Oxypharma	Rob 895	Multiple sclerosis	CNS		●●
Oxypharma	Rabeximod	Rheumatoid arthritis	Rheumatology		●●
ParkCell	Cell therapy	Parkinson's disease	CNS	Available	●●
ParkCell	N/A	N/A	Transplantation	Available	●●
Peptonic Medical	Oxytocin	Mild to severe symptoms of Vaginal Atrophy	Gynecology	Available	●●●●●
Pharmalink	Nefecon	Inflammatory kidney disease (IgA nephropathy)*	Nephrology		●●●●●
Pharma-lundensis	IodoCarb	Chronic obstructive pulmonary disease	Pulmonary		●●●●●
Pharmanest	SHACT , 4 lidocaine	Pain relief during IUD placements	Pain		●●●●●●
Pharmanest	SHACT , 4 lidocaine	Pain relief during gynecological procedures	Pain		●●●●●●
PharmNovo	PL6047	Neuropathic pain	Pain		●●
PharmNovo	PL6047	N/A	Pain		●●
PharmNovo	N/A	Migraine and osteoarthritis	Rheumatology		●
Pila Pharma	TRPV1-antagonists	Type-2 diabetes	Diabetic/ Metabolism		●●
PledPharma	PledOx	Chemotherapy Induced Peripheral Neuropathy	CNS		●●●●●
PledPharma	Aladote	Paracetamol (acetaminophen) acute liver failure*	Gastro-Intestinal		●●
Promore Pharma	PXL01	Prevention of adhesions after tendon and nerve repair	Other	Partner	●●●●●●
Promore Pharma	LL-37	Venous leg ulcers	Inflammation	Available	●●●●●
Promore Pharma	LL-37	Diabetic foot ulcers	Diabetic/ Metabolism	Available	●●●
Promore Pharma	PXL01	Prevention of adhesions after total knee arthroplasty	Other	Available	●●●
Promore Pharma	PXL150	Uncomplicated skin and skin structure infections	Dermatology	Available	●●
ProNoxis	N/A	Severe Autoimmunity – CIDP	Inflammation	Available	●
QuiaPEG Pharmaceuticals	N/A	Metabolic diseases	Diabetic/ Metabolism		●●
QuiaPEG Pharmaceuticals	N/A	N/A	Inflammation		●
QureTech Bio	Virulence blockers	Tuberculosis (Drug resistant)	Infection	Available	●

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Pipeline 2016

COMPANY	COMPOUND	INDICATION	THERA- PEUTIC AREA	PART- NERING STATUS	PHASE
QureTech Bio	Virulence blockers	MRSA & VRE (Gram positive)	Infection	Available	●
QureTech Bio	Virulence blockers	Chlamydia	Infection	Available	●
Red Glead Discovery	N/A	Acute Myeloid Leukemia	Oncology		●
Redwood Pharma (publ)	Small molecule	Dry eye disease	Ophthalmology	Available	●●●●
Respiratorius	VAL-001	Lymphoma*	Oncology		●●●●
Respiratorius	RESP-3000	Cardiovascular perfusion	Cardio- vascular		●
Respiratorius	RESP-1000	COPD – Asthma	Pulmonary		●
Respiratorius	RESP-200	COPD – Asthma	Pulmonary		●
Rhovac	RV001	Immunotherapy	Immuno- Oncology		●●
RSPR Pharma	CRD007	Asthma	Pulmonary	Available	●●●●
ScandiCure	STK25 antagonists	Anti-diabetic	Diabetic/ Metabolism		●
Scandinavian Biopharma	Enterotoxigenic E. coli	Diarrheal disease	Gastro- Intestinal	No answer	●●●●
Sixera Pharma	Proteases inhib- itors	Netherton syndrome	Dermatology		●●
Spago Nanomedical	N/A	Solid tumors	Oncology	Available	●
Spago Nanomedical	N/A	Solid tumors	Oncology	Available	●
Sprint Bioscience	SB01328 and SB01683	Triple negative breast cancer	Oncology	Available	●
Sprint Bioscience	STK25	Type-2 diabetes	Diabetic/ Metabolism	Available	●
Sprint Bioscience	N/A	Acute Myeloid Leukemia	Oncology	Partner	●
Stayble Therapeutics	N/A	Discogenic chronic low back pain	Pain	Available	●●
Swedish Orphan Biovitrum (publ)	Orfadin (nitisinone)	Alkaptonuria – clinical*	Endocrinology	No answer	●●●●●●
Swedish Orphan Biovitrum (publ)	Kineret (anakinra)	Still's disease – clinical stage*	Rheumatology	No answer	●●●●●●
Swedish Orphan Biovitrum (publ)	Kineret (anakinra)	Acute gout – clinical stage*	Rheumatology	No answer	●●●●●●
Swedish Orphan Biovitrum (publ)	SOBI003	MPS3A, Sanfilippos disease*	Endocrinology	No answer	●●
Swedish Orphan Biovitrum (publ)	SOBI005	C5 driven diseases – preclinical*	Genetics	No answer	●●
Swedish Orphan Biovitrum (publ)	XTEN-FVIII	Haemophilia a – preclinical*	Hematology	In-Licensed	●●
Synphora	Latanoprost	Menière's disease	Otorhinol- aryngology		●●●●●●
Synphora	Latanoprost	Sound induced tinnitus	Otorhino- laryngology		●●

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* Orphan indication

COMPANY	COMPOUND	INDICATION	THERA- PEUTIC AREA	PART- NERING STATUS	PHASE
Tikomed	IBsolvMIR	Regenerative Medicine – Diabetes type 1*	Diabetic/ Metabolism		●●●●●●
Tikomed	TM-700	Ischemia	Cardiovas- cular		●●●●
Tikomed	TM-500	MS / CNS	CNS		●●●●
Toleranzia	Tolerogen	Myasthenia Gravis	Immunology	Available	●●●●
Toleranzia	Tolerogen	Myasthenia Gravis	Immunology	Available	●●●●
Trophea	N/A	Skin atrophy	Dermatology	Available	●●●●
Umecrine	GABA-A modulat- ing steroid antag- onists	Prader-Willi syndrome, obesity, overeating	CNS	Available	●●●●
Umecrine Cognition	GR3027	Hepatic Encephalopathy	Gastro- Intestinal		●●●●
Vicore Pharma	C21	Idiopathic pulmonary fibrosis (IPF)*	Pulmonary	Available	●●●●
Vicore Pharma	C21	Pulmonary arterial hypertension (PAH)*	Pulmonary	Available	●●●●
Vicore Pharma	C21	Spinal cord injuries*	CNS	Available	●●●●
Vivolux	VLX600	Solid tumors	Oncology		●●●●
Vivolux	VLX1570	Multiple myeloma	Oncology		●●●●●●
Vivolux	VLX1570	Waldenström's disease	Oncology		●●●●
Vivolux	VLX600	Radiotherapy	Oncology		●●●●
Wilson Therapeutics	WTX101	Wilson Disease*	Genetics	Other	●●●●●●
Wilson Therapeutics	WTX101	SOD1-fALS*	Genetics	Other	●●●●
WntResearch	Foxy-5	Breast cancer	Oncology	Available	●●●●
WntResearch	Foxy-5	Colon cancer	Oncology	Available	●●●●
WntResearch	Foxy-5	Prostate cancer	Oncology	Available	●●●●
WntResearch	Box-5	Gastric cancer	Oncology	Available	●●●●
WntResearch	Box-5	Malignant melanoma	Oncology	Available	●●●●
Xbrane Biopharma	Spherotide	Prostate cancer	Oncology	Available	●●●●
Xbrane Biopharma	Xlucane	Wet form of age related macular generation	Ophthalmology	Available	●●●●
Xintela	Cell therapy	Articular cartilage damage	Other		●●●●
Xspray Microparticles	XS003	Leukemia	Oncology		●●●●
Xspray Microparticles	XS004 GENERIC	Leukemia	Oncology		●●●●
Xspray Microparticles	XS004 IMPROVED	Leukemia	Oncology		●●●●

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An active year for Swedish biotech and pharmaceutical companies

The Swedish life science industry is constituted of 1 391 companies within all major sectors – pharma, biotech and medtech. Of these, around 890 are running research and development programs based in Sweden (Tillväxtanalys PM 2016:04).

This report includes 144 Swedish companies actively developing pharmaceutical drugs, of which 67 companies have projects in clinical phase I–III.

This report provides you with an in-depth analysis of the clinical research projects, an overview of the preclinical projects as well as company information, including geographical location, statistics on number of employees and more.

This year's edition also includes an exclusive list of all clinical and preclinical projects, showcasing the Swedish pipeline compounds, indications therapeutic areas and clinical stage progression stage of development. The list can be found at the end of the report.

Key findings in the 2016 report include:

- ▶ In total, there are currently 369 projects in the pipeline, of which 144 are in clinical development.
- ▶ Since last year's report four products were approved for new markets and two market approvals are pending.
- ▶ Oncology projects dominate, making up 30% of the clinical pipeline.
- ▶ One third of the clinical research projects target an orphan indication, and a record high number of companies were granted orphan designation by EMA and/or FDA in 2015.
- ▶ Special highlight on women's health this year revealed 22 projects in the pipeline.
- ▶ Ten new companies were founded in 2015, and twelve companies were listed on the Swedish stock exchange.

The report has been published annually since 2006 by SwedenBIO, the Swedish Life Science Industry Organization (www.swedenbio.se).