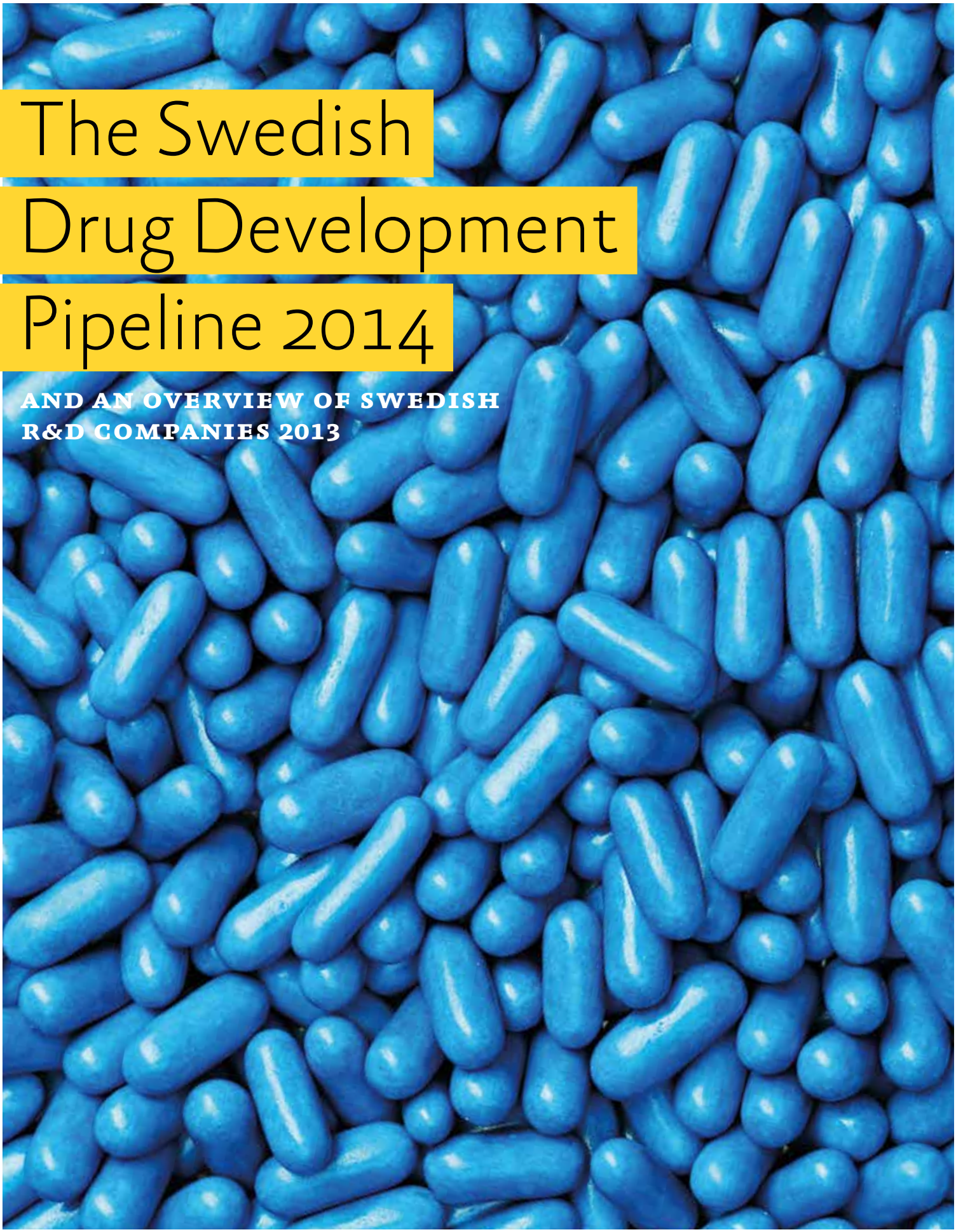

The Swedish Drug Development Pipeline 2014

AND AN OVERVIEW OF SWEDISH R&D COMPANIES 2013

DECEMBER 2014 THIS REPORT IS COMPILED BY SWEDENBIO WITH SUPPORT FROM VINNOVA

VINNOVA

The Swedish Life Science Industry Organization
swedenBIO

CONTENT

INTRODUCTION

A growing number of projects in a dynamic pipeline

The Swedish Life Science industry holds around 1 500 companies active in pharma, biotech and medtech. Of these, 800 are engaged in research and development programs in Sweden (Vinnova Analysis 2014:13).

This report highlights 98 companies actively developing novel drugs. Compared to last year, 16 of the companies are new on the list and 17 companies have left the list due to mergers, bankruptcy etc. The significant turnover of companies on the list stresses the dynamic character of this industry sector.

As described in previous pipeline reports, a majority of the clinical projects accumulate in phase II where they seem to get stuck. When asked why the projects do not progress further, the companies mention lack of funding and trouble finding the right partner as major reasons.

Still, compared to last year's report an increased number of projects have moved from one phase to another. Since the last report 33 projects have changed status from preclinical to clinical or from one clinical phase to another. Last year only 7 projects reported to have changed status. In that respect it seems to have been a successful year in the Swedish drug development pipeline. In total we see an increased number of projects, which also is a positive signal.

There is a trend towards smaller companies. 86% of the companies covered in this report are micro companies with ten or less employees, compared to 81% the previous year. A significant part of the actual research is conducted in collaboration with research groups and other partners including external consultants and contract research organizations. This can probably be explained by a general trend in the global life science sector where more and more small virtual companies drive drug development. But then the question is why so few companies grow from micro to small and medium sized companies.

About the report

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

The projects being analyzed are future products for human use that reached clinical development, Phase I–III. Data and information in this report originates from a web-based survey and public information.

The report has been published annually since 2006 and is compiled by SwedenBIO, the Swedish Life Science Industry Organization (www.swedenbio.com). Financial support has been obtained from vinnova, the Swedish Governmental Agency for Innovation Systems (www.vinnova.se).

Contact information
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sara.gunneras@swedenbio.com

Material and method

Initially, a list of potentially relevant companies, both pre-clinical and clinical stage companies, was compiled. The list was based on the companies included in last year's report, and supplemented with companies from the database biotech gate (www.biotechgate.com) and companies that are mentioned in the Vinnova Analysis 2014: 13. A search for companies in Swedish science parks and incubators was also done. Several companies were contacted in order to confirm ongoing R&D activities.

During November 2014, the companies were contacted and asked about current pipeline status (web-based questionnaire). SwedenBIO also informed about the survey in a weekly newsletter and on the SwedenBIO website. In total, 43 companies answered the survey. For the remaining companies, pipeline information was collected from e.g. last year's report, company websites and www.clinicaltrial.gov.

Corporate information, i.e. financial figures 2013 and location was obtained from www.allabolag.se.

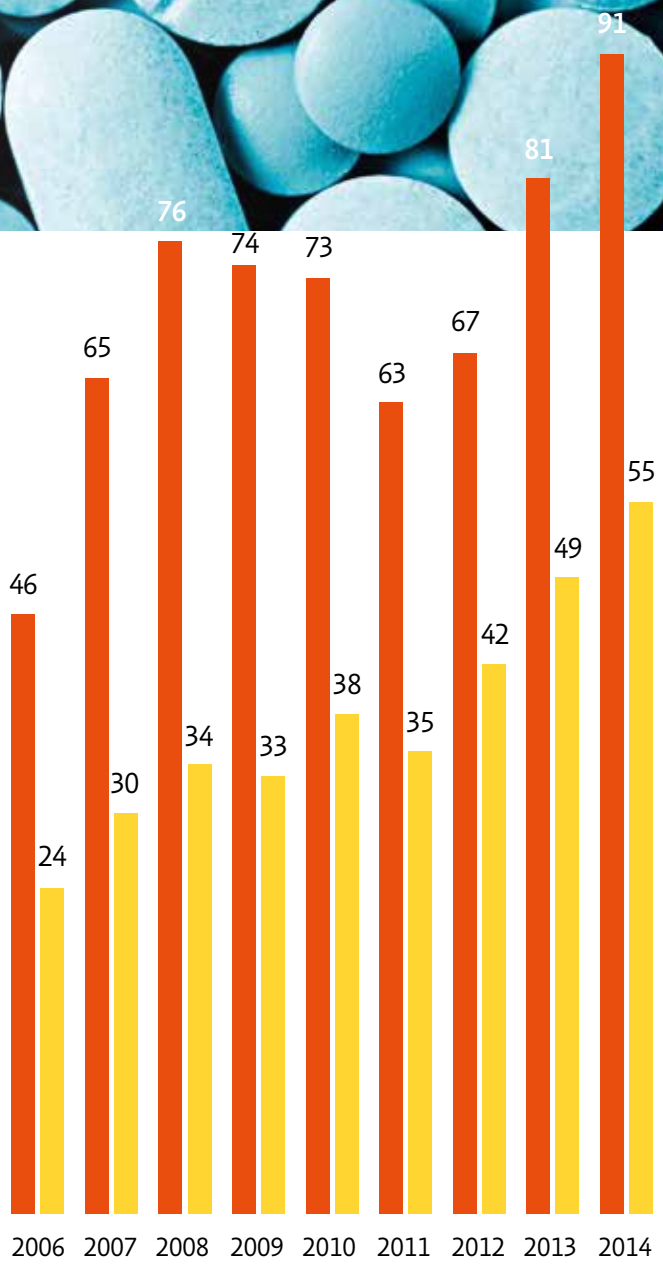
Data from previous reports, i.e. The Swedish Drug Development Pipeline report -06, -07, -08, -09, -10, -11, -12 and -13 were included for comparison. All reports may be downloaded from the SwedenBIO website: www.swedenbio.com/rapporter.

The Swedish drug development pipeline 2014

INCREASED NUMBER OF PROJECTS

The analysis reveals that there are 55 Swedish companies with a total of 91 projects in Phase I–III clinical trials. This is an increase as compared to last year when 81 projects were reported.

A product or molecule is commonly tested for more than one indication, e.g. one clinical trial for use in Alzheimer's disease and another for treating schizophrenia. In the current pipeline 73 of the 91 projects are unique entities, both small and large molecules, being evaluated for various indications. Of these 73 entities, 15 are being tested for two or more indications.



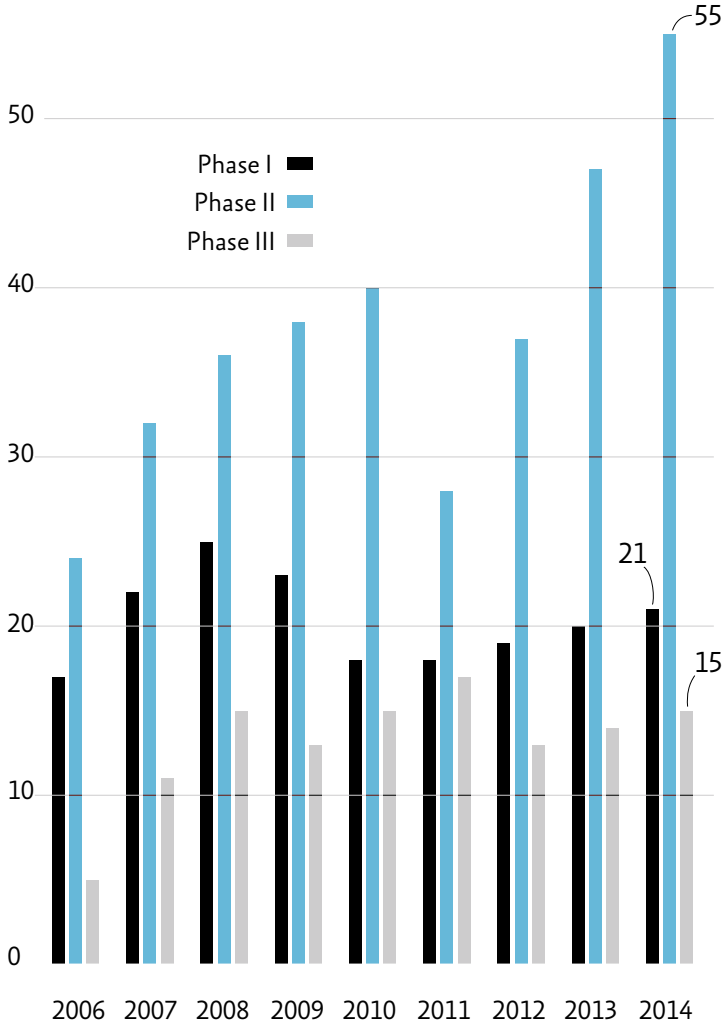
PROJECTS ACCUMULATE IN PHASE II

Most projects, 55, are in Phase II, 21 projects are in Phase I, and 15 in Phase III. Since the last report, 33 projects have changed status from preclinical to clinical or from one clinical phase to another. Last year only 7 projects reported to have changed status.

Projects reaching the market

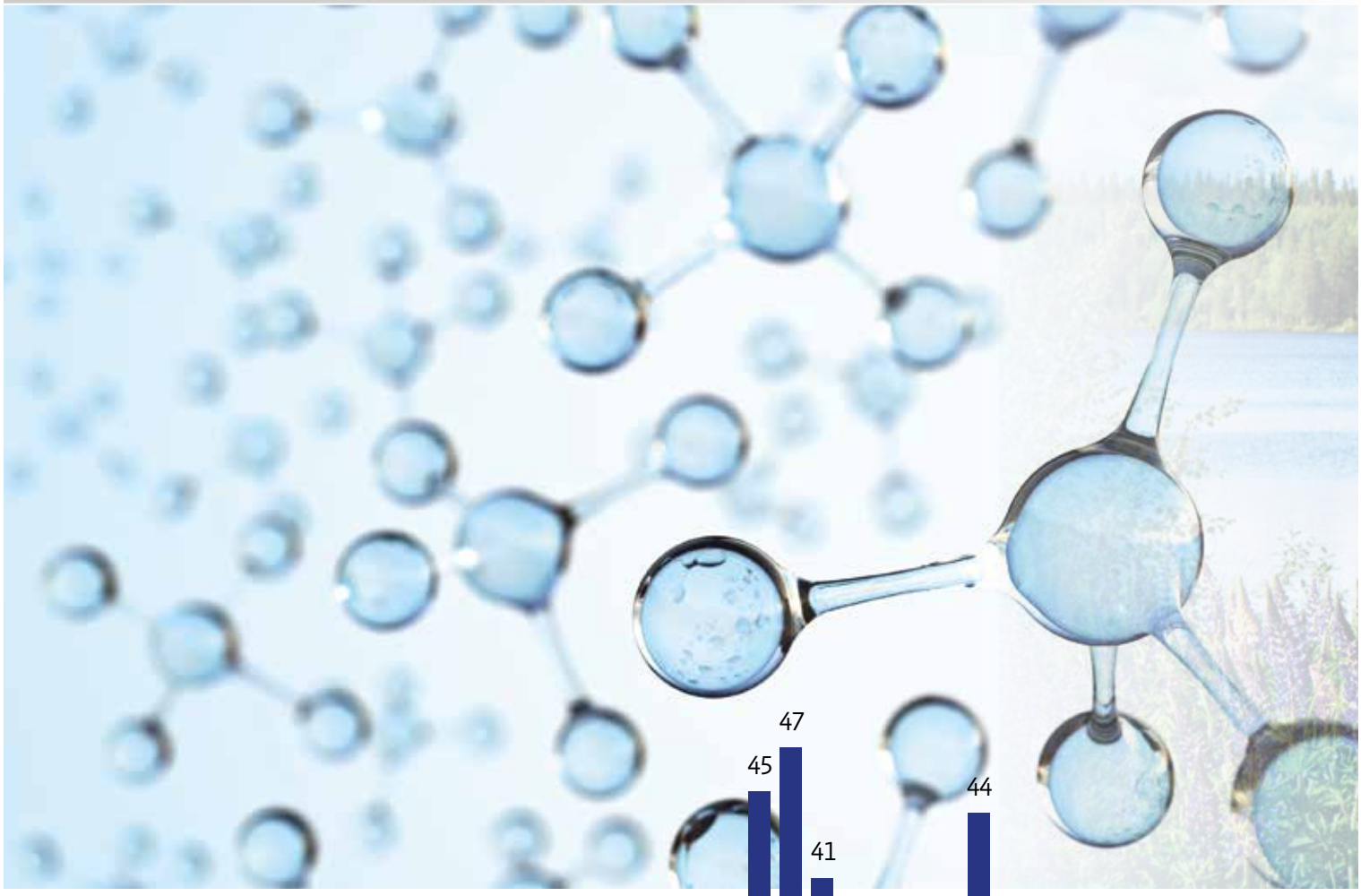
In July 2013, Orexo's Zubsolv (buprenorphine and naloxone) sublingual tablets (CIII) received approval from the U.S. Food and Drug Administration for the maintenance treatment of opioid dependence.

In October 2014, Oasmia Pharmaceuticals announced the full clinical trial report of Paclical, for the treatment of epithelial ovarian oncology and the result indicated a positive benefit profile. The data will serve as basis of a Marketing Authorization Application to the European Medicines Agency.



ONCOLOGY PROJECTS DOMINATE

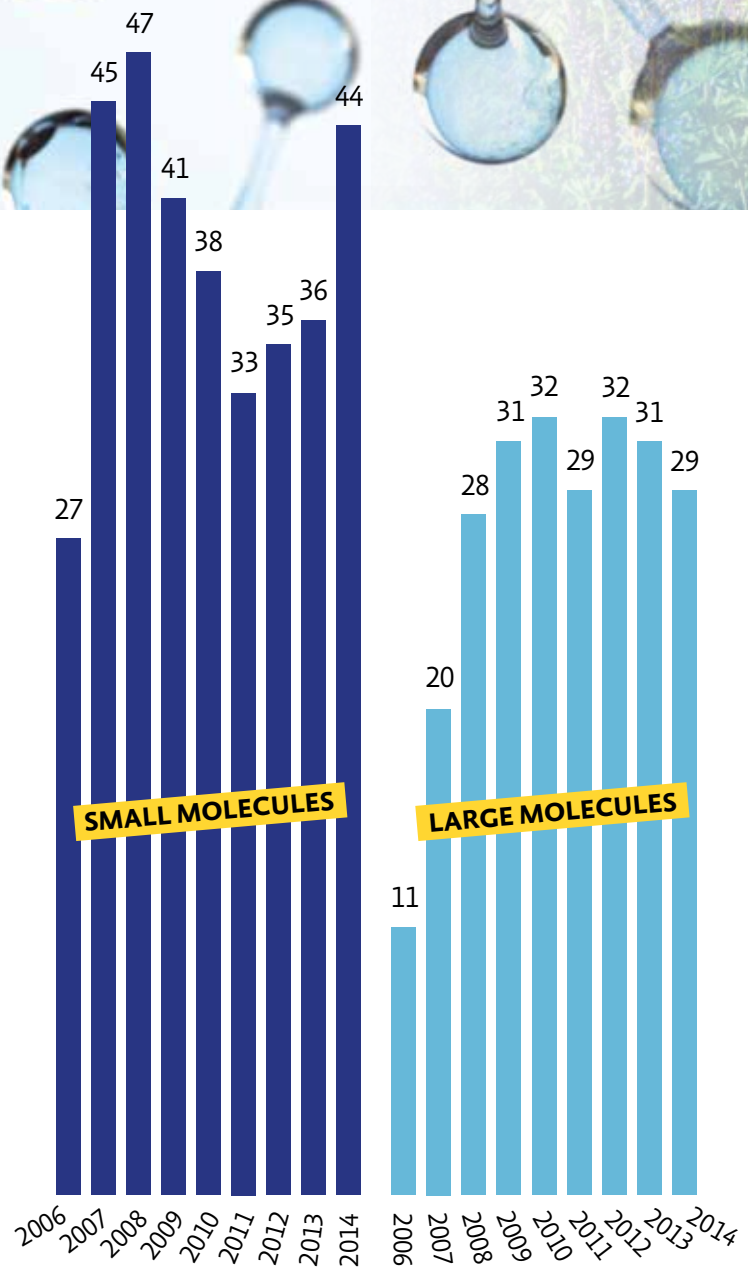
Oncology is one of the largest therapeutic areas in terms of drug development activity, addressing a disease area that causes more deaths than all other diseases apart from cardiovascular deseases. The Swedish pipeline is also dominated by oncology projects. Other strong areas are CNS and gastro-intestinal disorders. The category "Other" includes projects in the areas of e.g. osteoporosis and transplantation.



THE RETURN OF SMALL MOLECULES

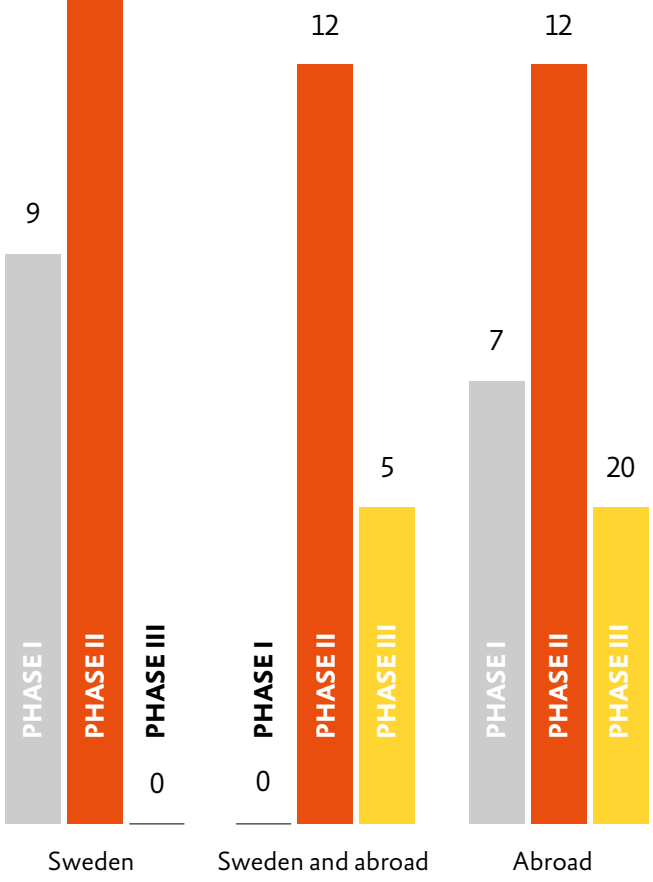
Small molecules make up the majority of drugs on the market today but large molecules, also known as biopharmaceuticals or protein-based molecules, are getting increased attention due to the great potential they have for diseases that still have high unmet medical needs.

The last few years report has shown stable numbers in terms of number and distribution between small and large molecules. However this year reveals an increase in the number of small molecular projects. 44 of the 73 products are small and 29 are large entities. The group of large molecules includes: antibodies, therapeutic vaccines, cell therapies, hormones and here also including the hybrid class of peptides.



SWEDEN STILL POPULAR FOR CLINICAL TRIALS

Both the number of clinical trials and the amount of patients included in the trials has decreased in total in Sweden during the last years. But when analyzing the 98 Swedish companies developing novel drugs, Sweden is still the preferred country for clinical trials. This result is similar to the previous year.

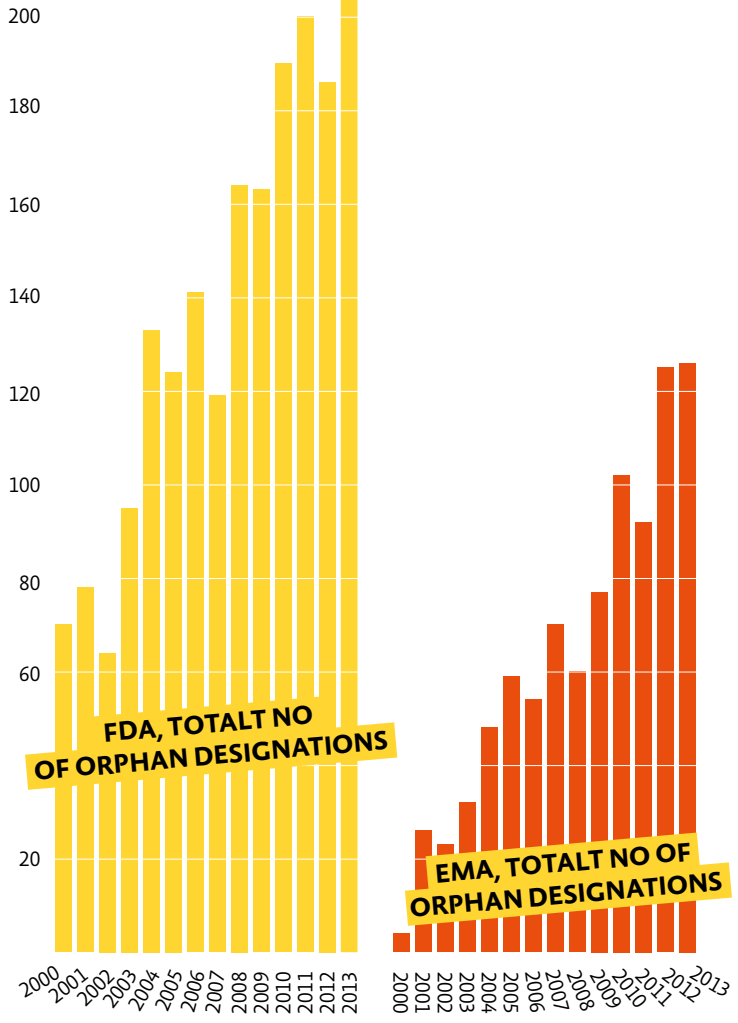


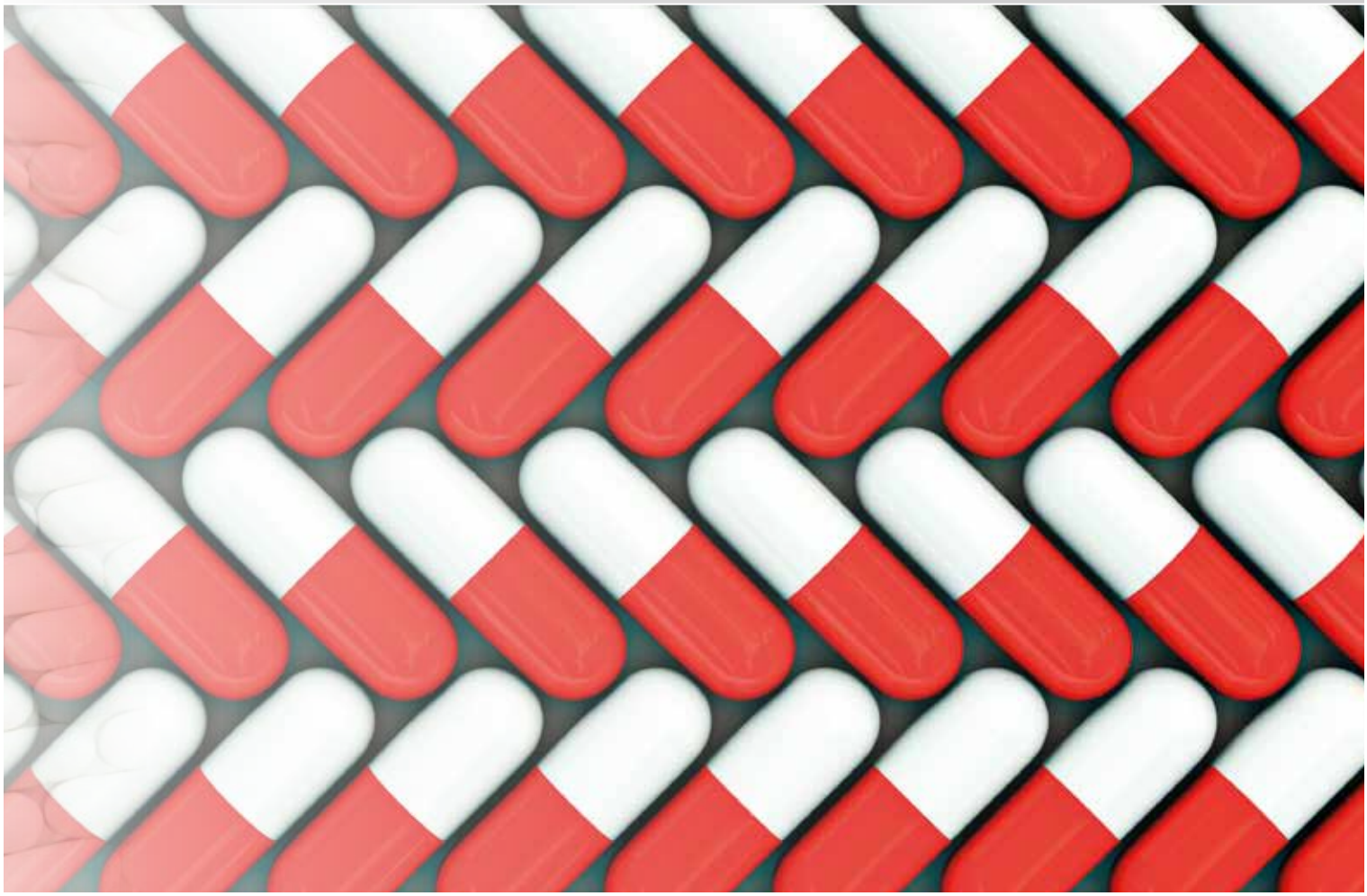
ORPHAN DRUGS

Developing a treatment for a rare disease is an emerging trend in drug development. A rare disease, or orphan disease, is any disease that affects a minor part of the population. Since development of pharmaceuticals is expensive, special incentives have been created to encourage biotech and pharma companies to conduct research on these diseases.

The market for orphan drugs is relatively small due to the low number of patients. However, total market value is estimated to $50 billion dollars by the end of 2011 (The Economic Power of Orphan Drugs, 2012, Thomson Reuters).

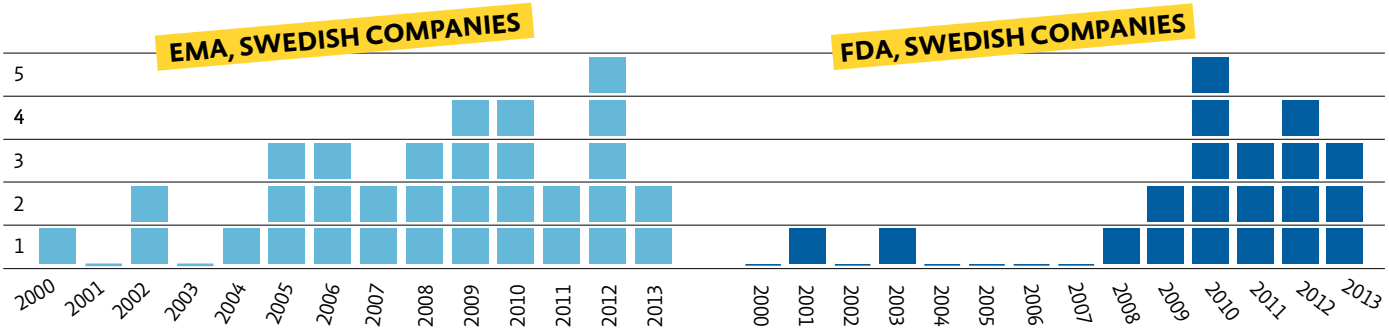
Since the year 2000 EMA and/or FDA granted Swedish companies orphan drug status for about 50 drugs.





According to the drug development pipeline survey this year, 22 of the projects in Phase I–III are targeting an orphan indication. During 2013 four Swedish companies got orphan drug designations granted from EMA and/or FDA:

- Infant Bacterial Therapeutics AB, use of L. reuteri for prevention of necrotizing enterocolitis in preterm infants
- iReg Medical AB, use of autologous regulatory T cells for prevention of graft rejection following solid organ transplantation
- Pharmalink AB, use of liposomal busulfan as a conditioning regimen for patients with malignancies undergoing autologous or allogenic hematopoietic stem cell transplantation
- Wilson Therapeutics AB, use of choline tetrathiomolybdate treatment of Wilson's disease.

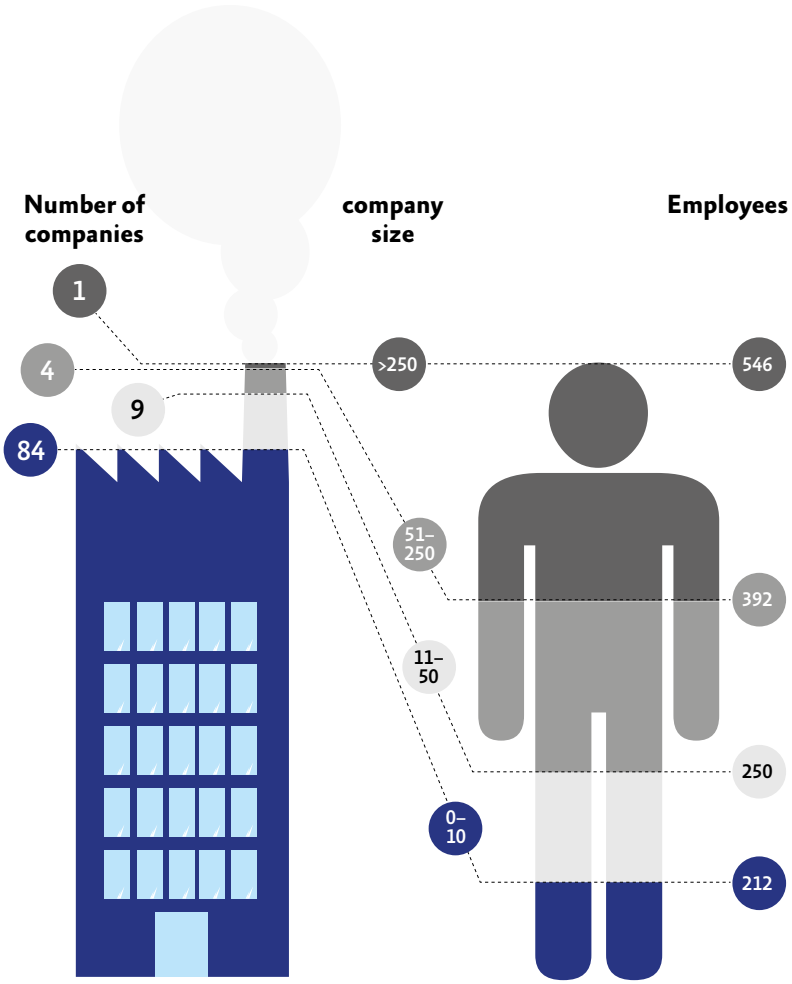


Drug developing Companies in Sweden

MANY MICRO COMPANIES

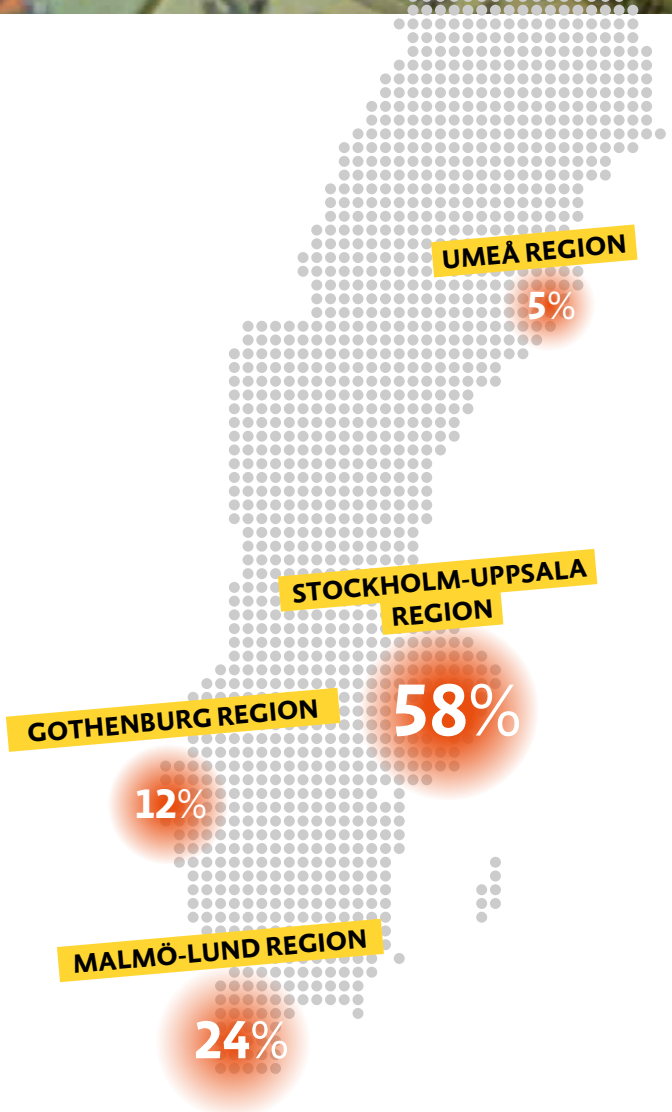
A total of 98 Swedish biotech and pharmaceutical companies with their head office in Sweden were identified to be actively working with drug development by the end of 2013. The companies had about 1 400 employees on their payroll in 2013. Four new registered companied were identified: Empros Pharma AB in Stockholm, iCell Science AB in Uppsala, ImmuneBiotech Medical Sweden AB in Lund and Integrative Research Laboratories Sweden AB in Gothenburg.

Most companies, 86 %, are micro-sized companies with 10 or fewer employees. This is 5% more than last year. With AstraZeneca excluded from the statistics in this report, Swedish Orphan Biovitrum is currently the only large research company in Sweden with more than 250 employees.



STOCKHOLM-UPPSALA THE LARGEST REGION

The companies are centered to four geographical regions. The majority of the companies, 58 % are located in the Stockholm-Uppsala region, followed by the Malmö-Lund region (24%), Gothenburg (12%) and Umeå (5%). About half of the drug developing companies are associated with a science park. Karolinska Science Park in Stockholm and Medicon Village in Lund are the two major science parks in terms of number of companies.



Companies listed by development phase

PHASE I

AcuCort	Other
Akinion Pharmaceuticals	Oncology
Alligator Bioscience	Oncology
AnaMar	Inflammation
Axcentua Pharmaceuticals	Oncology
Camurus	Oncology
	CNS
Cardoz	Other
Cebix	Endocrinology
Dextech	Oncology
Dilaforette	Infection
Galecto Biotech	Oncology
iCell Science	Diabetic/Metabolism
iCell Science	Transplantation
Immunicum	Oncology
Medivir	Other
Redwood Pharma	Other
Respiratorius	Oncology
Scandinavian Biopharma	Infection
WntResearch	Oncology

PHASE II

Active Biotech	CNS
	immunsystem
Adenovir	Other
Affibody Medical	Oncology
Albireo	Gastro-Intestinal
AnaMar	Inflammation
	Inflammation
Apodemus	CNS
Aprea	Oncology
Axelar	Oncology
Bioarctic Neuroscience	CNS
Bioinvent	Oncology
Camurus	Oncology
Cebix	Endocrinology
Cormorant Pharmaceuticals	Oncology
Dextech	Oncology
Diamyd Medical	immunsystem
Dilafor	Other
Dilaforette	Infection
Eurocine Vaccines	Infection
Hansa Medical	Transplantation
Immunicum	Oncology

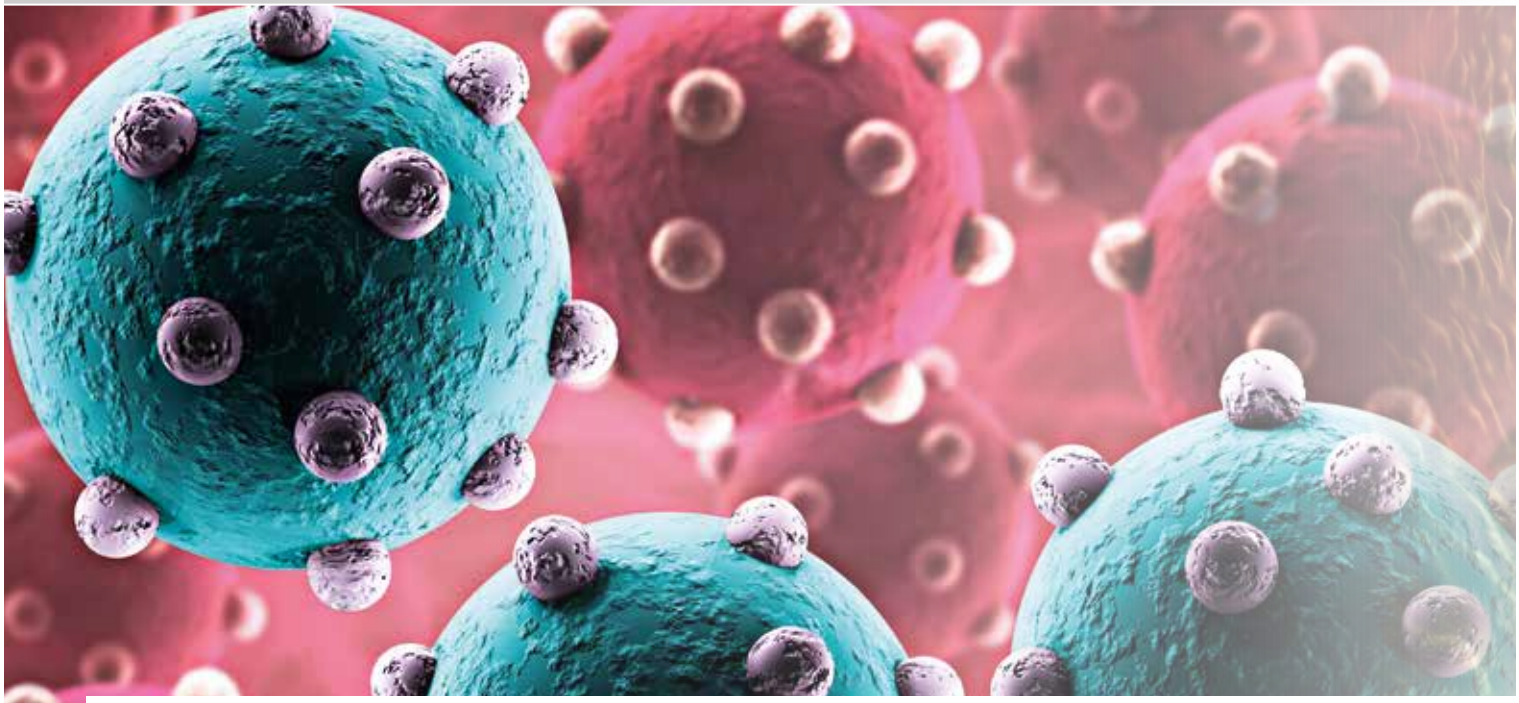
Companies listed by development phase

PHASE II CONTINUING

Isifer	immunsystem
	Other
LIDDS	Oncology
Lipidor	Dermatology
Moberg Pharma	Dermatology
	Pain
NeuroVive	CNS
Oncopeptides	Oncology
Orexo	Pain
OxThera	Diabetic/Metabolism
Peptonic Medical	Other
Pergamum	Dermatology
Pharmalink	Other
	Transplantation
Pharmalundensis	Other
Pharmanest	Pain
PledPharma	Oncology
	Cardiovascular
Synphora	Pain
TikoMed	Oncology
	Diabetic/Metabolism
Umecrine Mood	CNS
Wilson Therapeutics	CNS

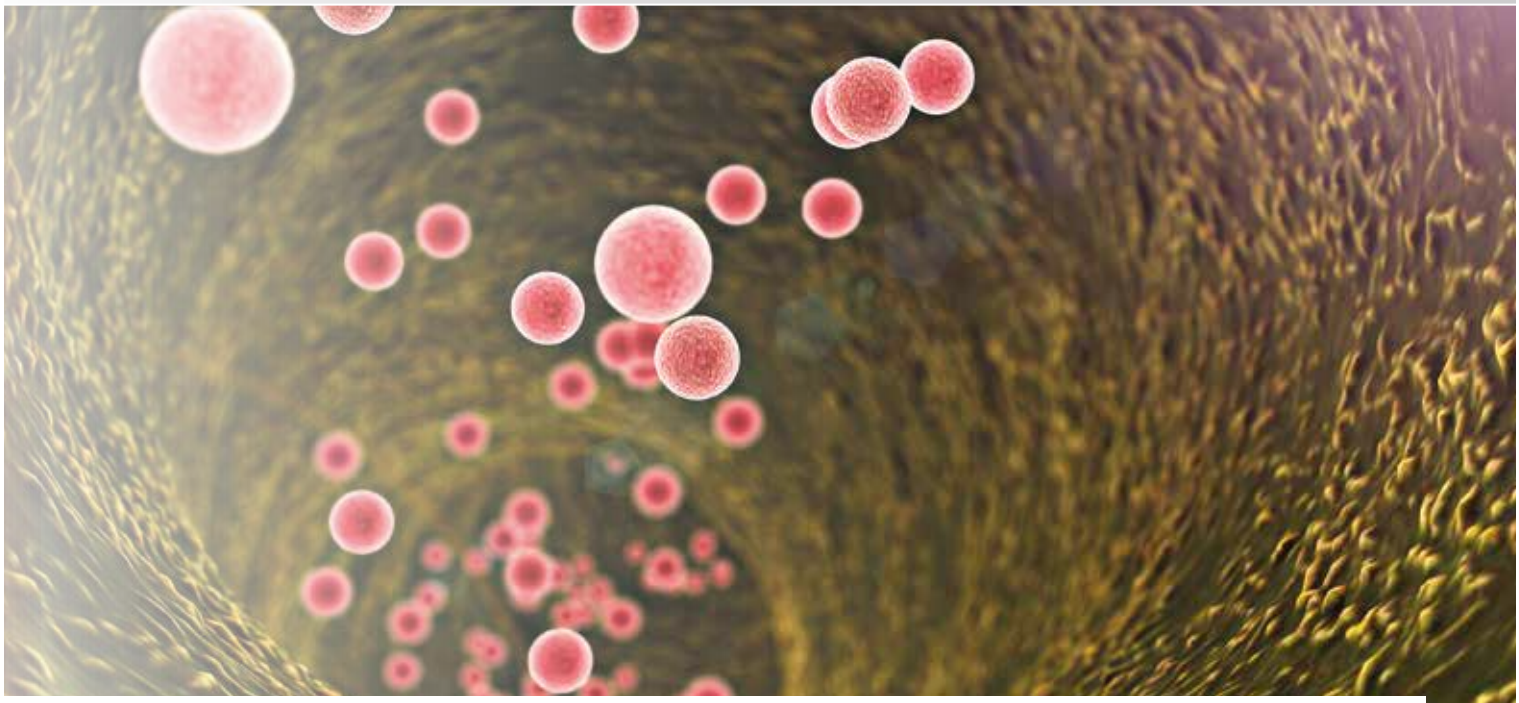
PHASE III

Active Biotech	CNS
Albireo	Gastro-Intestinal
Camurus	CNS
	Endocrinology
Immun System I.M.S.	Infection
InDex Pharmaceuticals	Gastro-Intestinal
NeuroVive	Cardiovascular
Oasmia	oncology
Orexo	Other
SOBI	Gastro-Intestinal
	Other



Companies listed by therapeutic areas

ONCOLOGY	CNS	GASTRO-INTESTINAL	INFECTION	DIABETIC/ METABOLISM
Active Biotech	Active Biotech	InDex Pharmaceuticals	Dilaforette	iCell Science
Affibody Medical	Apodemus	SOBI	Eurocine Vaccines	OxThera
Akinion Pharmaceuticals	Bioarctic Neuroscience	Albireo	Immun System I.M.S.	TikoMed
Alligator Bioscience	Camurus	–	Scandinavian Biopharma	–
Aprea	NeuroVive	–	–	–
Axcentua Pharmaceuticals	Umecrine Mood	–	–	–
Axelar	Wilson Therapeutics	–	–	–
Bioinvent	–	–	–	–
Camurus	–	–	–	–
Cormorant Pharmaceuticals	–	–	–	–
Dextech	–	–	–	–
Galecto Biotech	–	–	–	–
Immunicum	–	–	–	–
Isofol	–	–	–	–
LIDDS	–	–	–	–
Oasmia	–	–	–	–
Oncopeptides	–	–	–	–
PledPharma	–	–	–	–
Respiratorius	–	–	–	–
TikoMed	–	–	–	–
WntResearch	–	–	–	–



Companies listed by therapeutic areas

DERMATOLOGY	PAIN	INFLAM-MATION	ENDO-CRINOLOGY	OTHER
Moberg Pharma	Moberg Pharma	AnaMar	Camurus	Active Biotech
Lipidor	Orexo	–	Cebix	AcuCort
Pergamum	Pharmanest	–	–	Adenovir
–	Synphora	–	–	Cardoz
–	–	–	–	Diamyd Medical
–	–	–	–	Dilafor
–	–	–	–	Hansa Medical
–	–	–	–	iCell Science
–	–	–	–	Isifer
–	–	–	–	Isifer
–	–	–	–	Medivir
–	–	–	–	NeuroVive
–	–	–	–	Orexo
–	–	–	–	Peptonic Medical
–	–	–	–	Pharmalink
–	–	–	–	Pharmalundensis
–	–	–	–	PledPharma
–	–	–	–	Redwood Pharma
–	–	–	–	SOBI
–	–	–	–	
–	–	–	–	

Top 10 list of largest companies by number of employees

COMPANY	FTE 2013	TURNOVER 2013 (TSEK)	HEAD OFFICE	THERAPEUTIC AREA	OWNER	FOUNDED
Swedish Orphan Biovitrum	546	2200318	Stockholm	Rare diseases: inflammation, genetics & metabolism.	Public	1939
Medivir	153	452493	Stockholm	Infectious diseases: hepatitis C.	Public	1987
Orexo	106	447019	Uppsala	Specialty pharma and drug delivery technology.	Public	1995
Oasmia Pharmaceutical	72	51159	Uppsala	Nanoparticle formulations and drug-delivery systems based on well-established cytostatics	Public	1988
Active Biotech	61	115970	Lund	Immunology: multiple sclerosis and oncology.	Public	1983
BioInvent International	47	82651	Lund	Antibody therapeutics: treatment of oncology.	Public	1997
Karo Bio	40	50705	Stockholm	Nuclear receptors: neuropsychiatry, inflammation, autoimmune diseases and oncology.	Public	1987
Camurus	35	203066	Lund	Drug-delivery systems for development of high-value therapeutics.	Private	2004
Moberg Pharma	29	158457	Stockholm	Skin disease	Public	2006
Bioarctic Neuroscience	28	58752	Stockholm	Neurodegenerative diseases (alzheimer)	Private	2000

Source: www.allabolag.se Information about Oasmia Pharmaceutical is from 2013-04

Top 10 list of largest companies by turnover

COMPANY	FTE 2013	TURNOVER 2013 (TSEK)	HEAD OFFICE	THERAPEUTIC AREA	OWNER	FOUNDED
Swedish Orphan Biovitrum	546	2200318	Stockholm	Rare diseases (inflammation, genetics & metabolism)	Public	1939
Medivir	153	452493	Stockholm	Infectious diseases (hepatitis C)	Public	1987
Orexo	106	447019	Uppsala	Specialty pharma and drug delivery technology	Public	1995
Camurus	35	203066	Lund	Drug-delivery systems	Private	2004
Moberg Derma	29	158457	Stockholm	Skin diseases	Public	2006
Active Biotech	61	115970	Lund	Immunology (multiple sclerosis) and oncology.	Public	1983
BioInvent International	47	82651	Lund	Antibody therapeutics: treatment of oncology.	Public	1997
Affibody	21	68183	Stockholm	Next generation biopharmaceuticals based on its technology platforms.	Public	2004
Bioarctic Neuroscience	28	58752	Stockholm	Neurodegenerative diseases (alzheimer)	Private	2000
Oasmia Pharmaceutical	72	51159	Uppsala	Nanoparticle formulations and drug-delivery systems (cytostatics)	Public	1988

Source: www.allabolag.se Information about Oasmia Pharmaceutical is from 2013-04

Companies A–Z

A1M Pharma
Active Biotech
AcuCort
Adenovir Pharma
Affibody Medical
Akinion Pharmaceuticals
Albireo
Alligator Bioscience
AlzeCure Foundation
Alzinova
Anamar
Apodemus
Aprea
Athera Biotechnologies
Axcentua Pharmaceuticals
Axelar
Betagenon
Bioarctic Neuroscience
Biocrine
Biognos
BioInvent International
Camurus
Canimguide Therapeutics
Cantargia
Cardoz
Cebix
Chemilia
ChronTech Pharma
ClanoTech
Cormorant Pharmaceuticals
Cortendo
Dextech Medical
Diamyd Medical
Dilafor
Dilaforette
Duecom Plus-A
Empros Pharma
Eurocine Vaccines
Follicum
Galecto Biotech
Glactone Pharma
Glucox Biotech
Grespo
Hansa Medical
Helicure
iCell Science
Immun System I.M.S.
ImmuneBiotech
Immunicum
InDex Pharmaceuticals
Infant Bacterial Therapeutics
Integrative Research Laboratories Sweden
Isifer
Isofol Medical

Companies A–Z

Kancera
Karo Bio
LIDDS
Lipidor
Lipigon Pharmaceuticals
Medivir
Moberg Pharma
Molecules of Man
NeuroVive Pharmaceutical
Northern Light Pharmaceuticals
NovaSAID
Noviga Research
Oasmia Pharmaceutical
Omnio Healer
Oncopeptides
Oncorena
Orexo
OxThera
PEPTONIC medical
Pergamum
Pharmalink
Pharmalundensis
Pharmanest
PledPharma
Red Glead Discovery
Redoxis
Redwood pharma
Respiratorius
Scandinavian Biopharma
Sprint Biosceince
Strongbone
Swedish Orphan Biovitrum
Synphora
TikoMed
Toleranzia
Umecrine
Umecrine Cognition
Umecrine Mood
Vicore Pharma
Vivolux
Wilson Therapeutics
WntResearch
XImmune
Xspray Microparticles

List of 98 companies that actively develop novel drugs in Sweden. Based on company information from December 31, 2013.

Astrazeneca a strong player in Sweden

ABOUT ASTRAZENECA

AstraZeneca is currently the only global pharmaceutical company with an R&D function in Sweden. The company has a strong presence in Sweden, with 5 745 employees (end of 2013) working with research, production and marketing. AstraZeneca has three global strategic research sites worldwide of which one is located in Mölndal outside Gothenburg. The R&D site has 2 200 employees and almost 25 percent of the global 28 BSEK R&D investment was made in Sweden (2013). The research in Mölndal is focused on heart and cardiovascular, metabolic, respiratory, inflamatory and autoimmunity diseases.

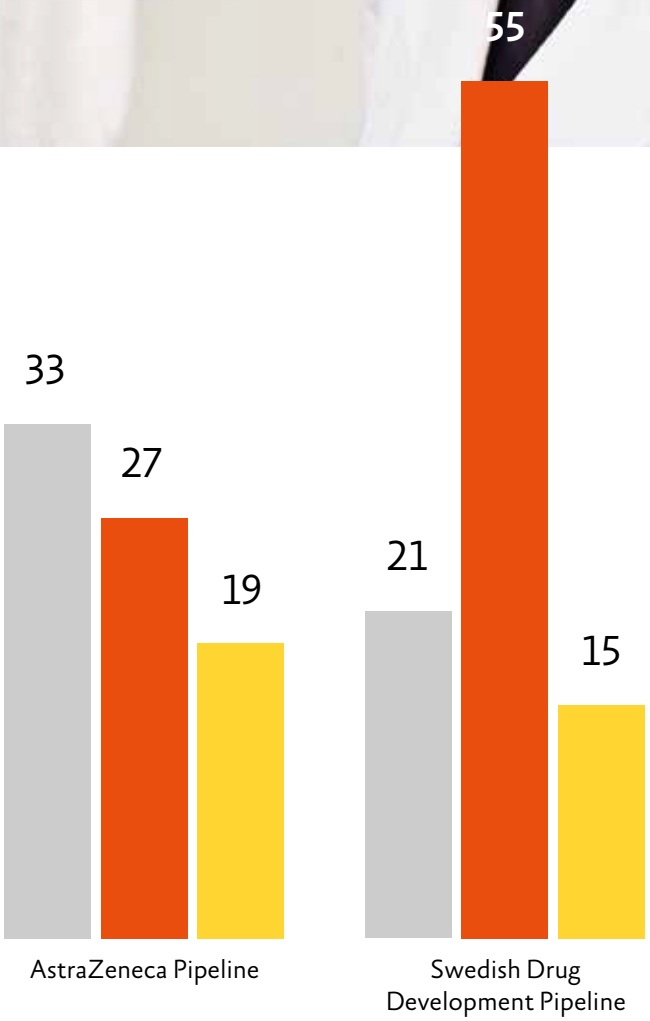
AstraZeneca was formed by the merger of Swedish Astra and British Zeneca in 1999. Astra was at that time one of the oldest Swedish pharmaceutical companies, founded in 1913. After the merger, AstraZeneca decided to locate their new HQ in London.

The Sweden-based R&D teams at Astra/AstraZeneca have developed world-leading products such as: Xylocain, Seloken, Bricanyl, Pulmicort, Symbicort, Losec and Nexium.

ASTRAZENECA'S DRUG DEVELOPMENT PIPELINE

Globally, AstraZeneca reported 85 projects in Phase I-III by the end of 2013. This is an increase with 20 projects compared to last year when 65 projects where reported. Most projects are in the therapeutic area of oncology, respiratory, cardiovascular and metabolic diseases. AstraZeneca's clinical pipeline currently has a 50-50 balance of small molecular programs and biologics. AstraZeneca reported additional 20 products in clinical trials that are line extensions, and where the majority is cardiovascular and metabolic disease.

In this report, we have chosen to make a comparison between AstraZeneca's and Sweden's pipeline. Interestingly, the size of the Swedish research company's portfolio corresponds to a global pharma company's portfolio, but the distribution of projects between Phase I-III is different.



Data was obtained from AstraZeneca's annual report presenting the pipeline status at the end of 2013. AstraZeneca does not divide their research portfolio into different national platforms. Phase III projects also include projects ready for registration.

PHOTO: ISTOCKPHOTO AND ASTRA ZENECA

A growing and dynamic pipeline

The Swedish Life Science industry holds around 1500 companies active in pharma, biotech and medtech. Of these, 800 are engaged in research and development programs in Sweden.

This report highlights 98 companies actively developing novel drugs. The projects analyzed are products for human use that reached clinical development, Phase I–III. Data and information in this report originates from a web-based survey and public information.

Key findings in the 2014 report include:

- There are 91 projects in Phase I–III. This is an increase compared to last year when 81 projects were reported.
- Most projects are in the area of oncology, followed by CNS and gastro-intestinal disorders.
- After some years of decrease of small molecular projects in the Swedish pipeline it seems that there is a trend with increasing number of small molecular projects.
- Swedish patients are included in two thirds of the ongoing clinical trials described in this report.
- Most companies, 86 %, are micro-sized companies with 10 or fewer employees. This is 5% more than last year.

The report has been published annually since 2006 and is compiled by SwedenBIO, the Swedish Life Science Industry Organization (www.swedenbio.com).
Financial support has been obtained from VINNOVA, the Swedish Governmental Agency for Innovation Systems (www.vinnova.se).

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