

The Swedish Drug Development Pipeline

& overview of Swedish companies with R&D activities in Sweden

December 2013



This report is compiled by SwedenBIO with support from VINNOVA and Business Sweden

The Swedish Life Science Industry Organization
swedenBIO



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Introduction

This report provide facts and figures about the current Swedish drug development pipeline.

The report has been published annually since 2006 and is compiled by SwedenBIO, the Swedish Life Science Industry Organization (www.swedenbio.com) with support from VINNOVA, the Swedish Governmental Agency for Innovation Systems (www.vinnova.se) and Business Sweden, the Swedish Trade & Invest Council (www.business-sweden.se).

The report focuses on Swedish companies with R&D in Sweden and their drug pipeline. The projects being analyzed are product 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 serves as a quantitative indicator of the progress of the Swedish drug pipeline compounds, projects and their characteristics. The report is used to promote Swedish drug development.

The report also includes information about the pipeline of AstraZeneca. Due to the large pipeline and that the research portfolio is not divided in different national platforms.

In addition, the report includes information about orphan drugs designations received by Swedish companies and a overview of biotech/pharma companies with R&D function in Sweden.

SwedenBIO, Busines Sweden and VINNOVA would like to thank all companies participating in the survey.

Key Findings

About **100 drug developing Swedish biotech and pharma companies** have R&D activities in **Sweden**. About 50% of these companies have ongoing clinical trials.

Development projects are distributed across many therapeutic areas, including cancer, infection, CNS and dermatological diseases. Development of new **cancer drugs** shows the greatest number of both preclinical and clinical projects.

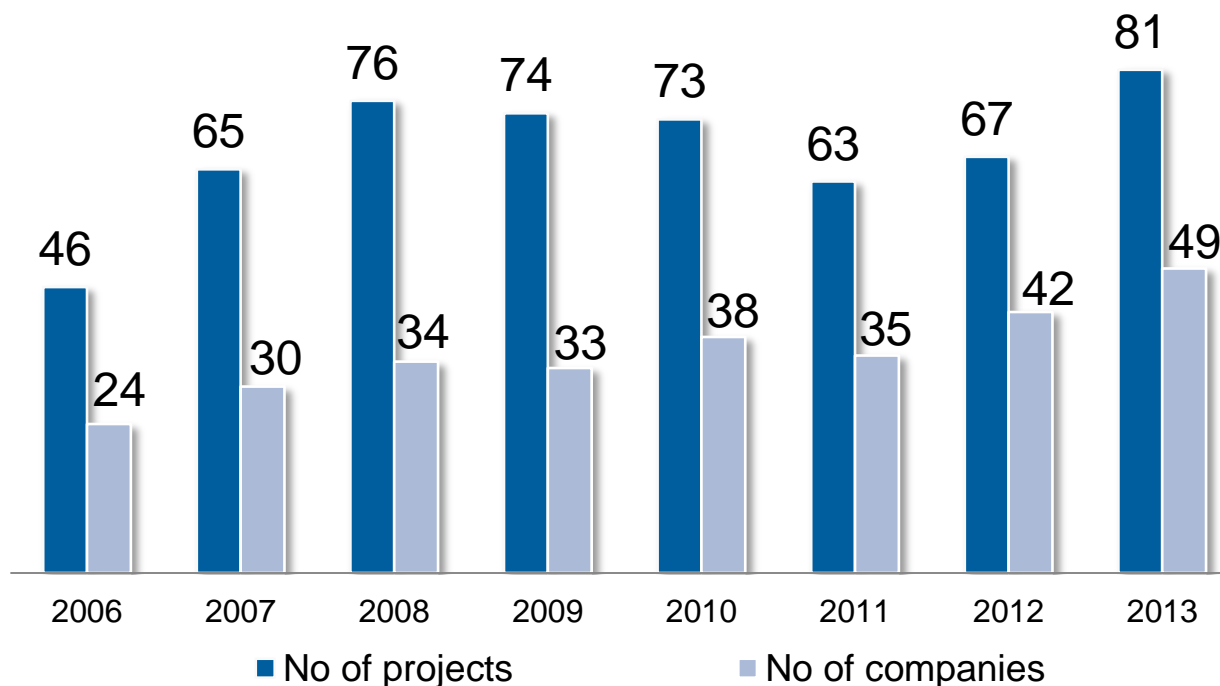
The drug development pipeline contain nearly **70 products in clinical development** (i.e. molecules which have advanced to clinical testing in human volunteers, but have not yet been launched).

Taking into account that a product may be undergoing clinical trials in more than one indication, there are currently about **80 projects in clinical development** (that is, unique molecule-indication combination).

- 14 of the projects are in Phase III.
- 7 of the projects reported last year progressed to next phase this year.

1 • Pipeline 2013

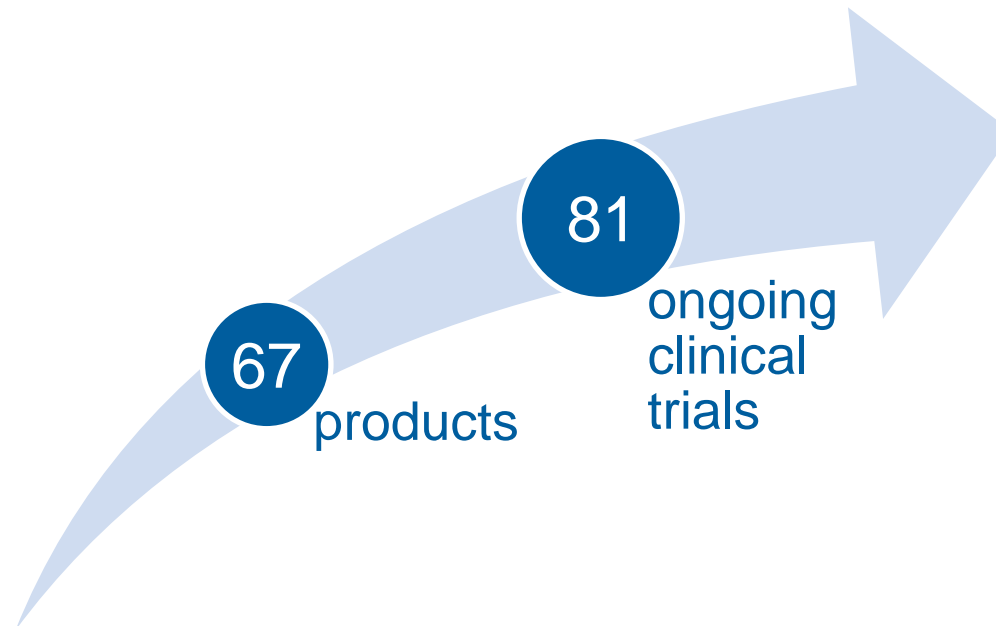
The current Swedish drug pipeline include at least 81 projects that reached clinical development stages, Phase I-III. The projects are developed by 49 companies. This year the web based survey was complemented with public information which may explain the increased number of both companies and projects.



Products and Projects

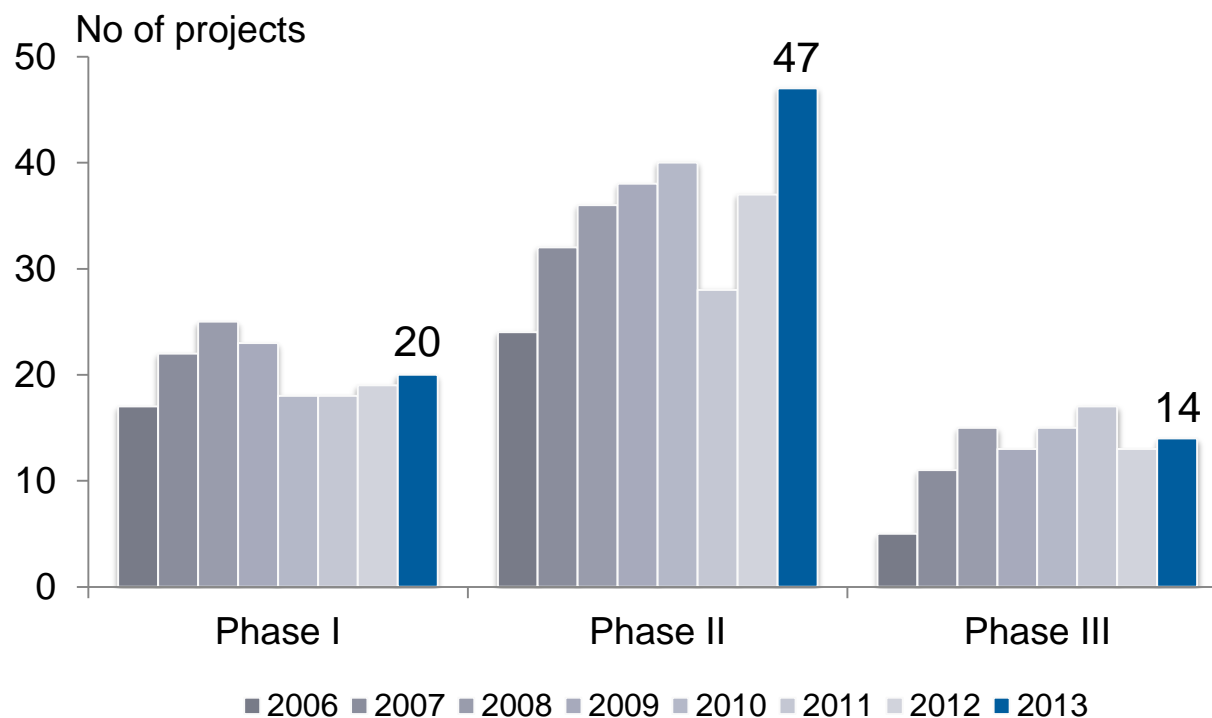
The current Swedish drug pipeline include at least 67 unique products, i.e. small and large molecules, that are being evaluated for various indications in 81 ongoing clinical trials, i.e. number of projects in Phase I-III.

- 11 of the 67 products are undergoing clinical trials in more than one indication e.g., a particular drug in clinical trials for use in Alzheimer's disease and schizophrenia would be counted as one product and two projects.



Projects by Phase and Progress from Last Year

Of the 81 ongoing clinical trials identified, most projects are in Phase II. Seven of the projects reported last year progressed to next phase this year. One Phase III project reported last year was filed for registration. 15 of the companies participating in the survey reported that they received clinical trial authorization during 2012 for Phase I-III studies.



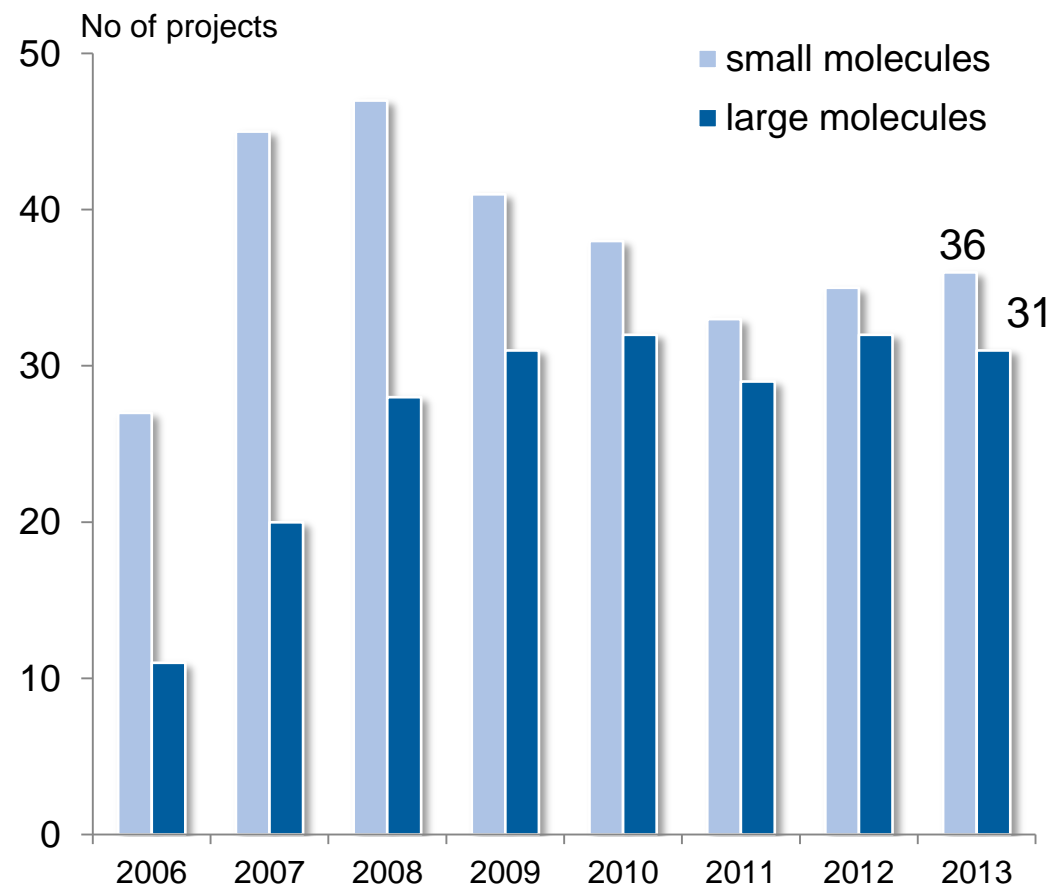
Small and Large Molecules

Small molecules make up the majority of drugs on the market today. Large molecules* are getting increased attention due to the great potential they have for diseases that still have high unmet medical needs.

- 36 of the 67 products are small molecules and 31 are large molecules.

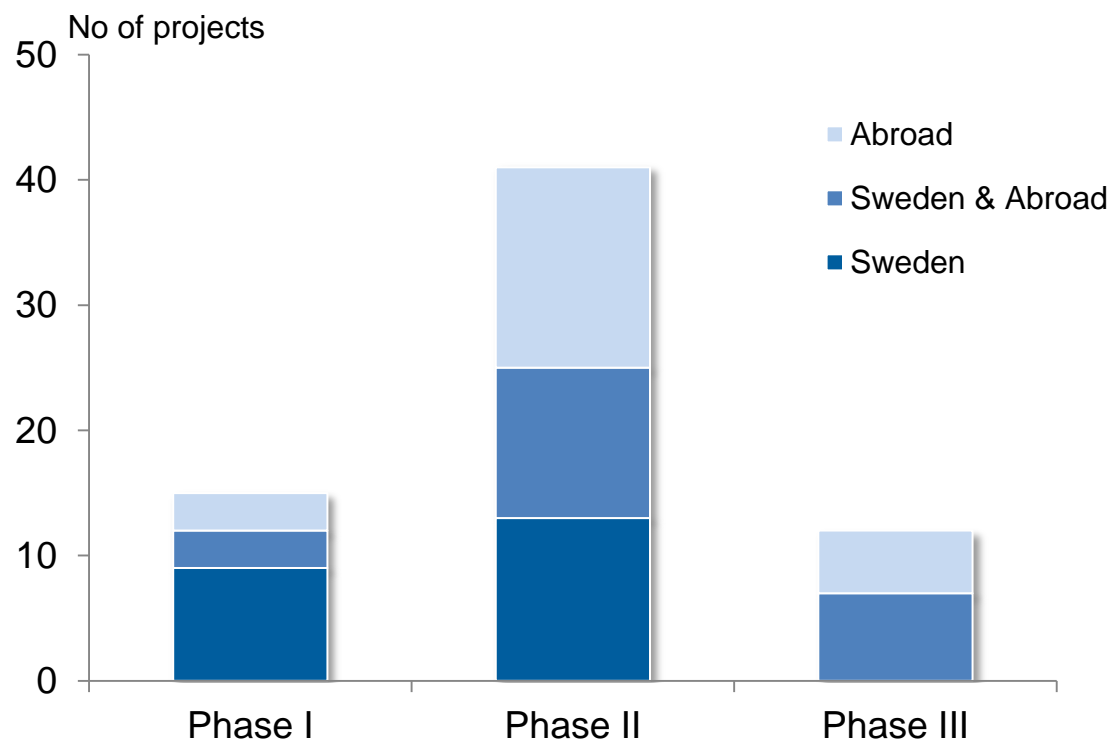
The group of large molecules include: antibodies, therapeutic vaccines, cell therapies, hormones and peptides.

*) also known as biologics or protein-based molecules, here also including the hybrid class of peptides)



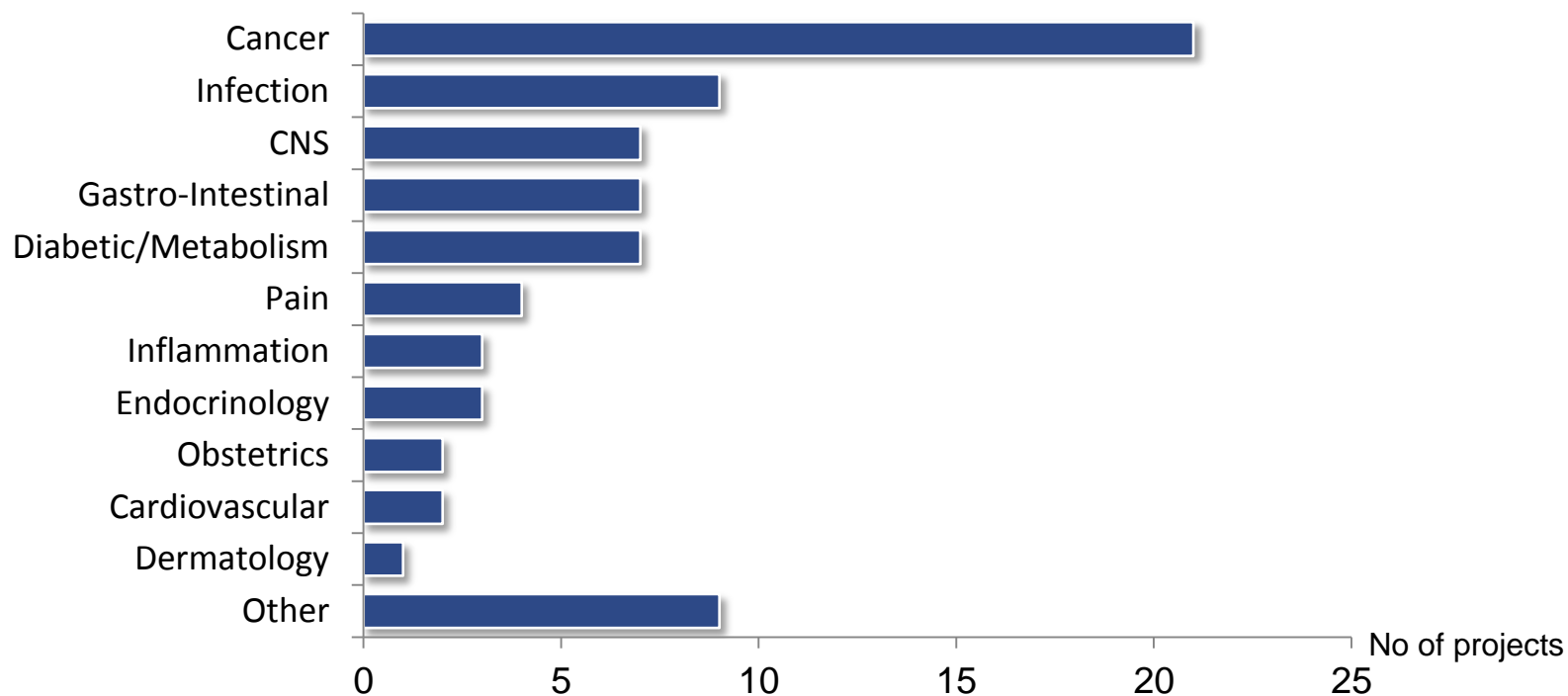
Choice of Country for Clinical Trial

Swedish patients are included in two thirds of the ongoing clinical trials. This result is similar to last years report. More than 50% of companies chose Sweden and Swedish subjects/ patients for Phase I and II trials and about 50 % include Swedish patients in their Phase III trial (response rate 85%).



Therapeutic Areas

Most projects currently in clinical development, Phase I-III, are in the area of cancer, followed by infection. The category “Other” include projects in the area of e.g. osteoporosis, transplantation and obstetrics.



2 • AstraZeneca

AstraZeneca is currently the only global pharmaceutical company with R&D function in Sweden.

AstraZeneca has a strong presence in Sweden, with approximately 5 800 employees (end of 2012) working with research, production and marketing. After several years of cutbacks, Mölndal in western Sweden remains the only research site in Sweden. The site is one of three global strategic research sites with research on heart / cardiovascular, metabolic, respiratory, inflammation and autoimmunity.

AstraZeneca was formed by the merger of Swedish Astra and UK firm Zeneca in 1999. Astra was at that time one of the oldest Swedish pharmaceutical companies, founded in 1913. After the merge, AstraZeneca moved the HQ from Stockholm to London.

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

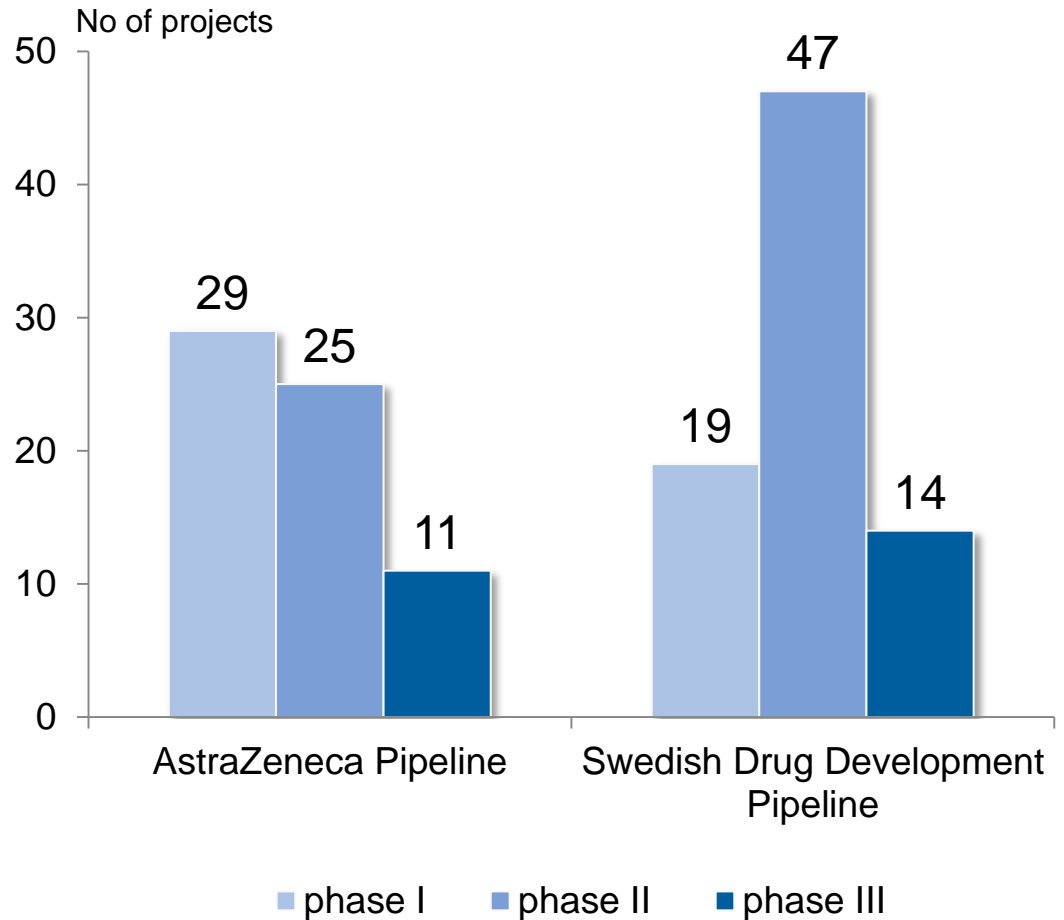
AstraZenecas pipeline are presented on page 12 in this report. Note that AstraZeneca does not divide their research portfolio in different national platforms. Phase III projects also include projects ready for registration. Data presented at the next page was obtained from AstraZenecas annual report presenting the pipeline status end of 2012.

AstraZeneca, Drug Development Pipeline 2012

Globally, AstraZeneca reported 65 projects in Phase I-III end of 2012.

- 40 projects are developed in collaboration with a partner and 25 projects are developed without a partner.
- Most projects are in the therapeutic area of cancer and respiratory/ inflammation.

AstraZeneca reported an additional 19 products in clinical trials that are line extensions.



Source: AstraZeneca annual report 2012

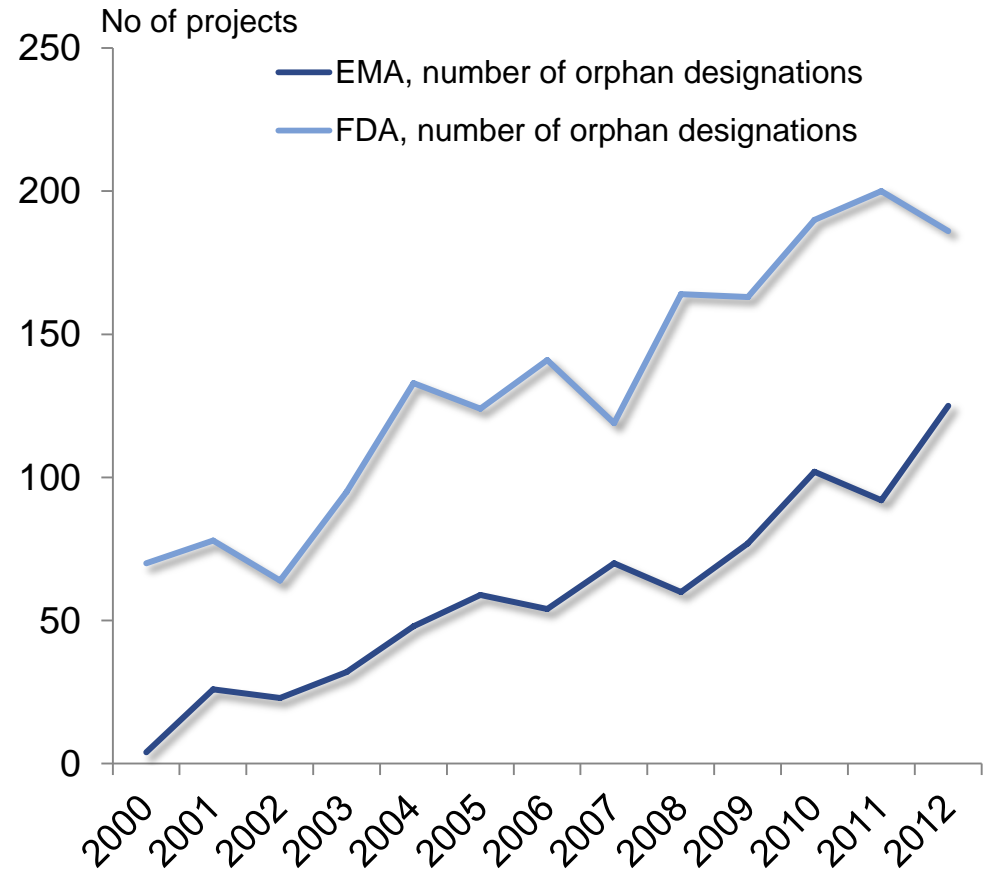
3 • Orphan Drugs

New treatments of rare diseases is an emerging trend in drug development.

A rare disease, or orphan disease, is any disease that affects a small percentage of the population. Since development of pharmaceuticals is expensive, special incentives have been created to encourage pharma and biotech companies to conduct research on these diseases.

Companies may apply for orphan drug designation, meaning that the sponsor qualifies for certain benefits, such as protocol assistance and reduced taxes from the federal government.

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 end of 2011*.



*) The Economic Power of Orphan Drugs, 2012, Thomson Reuters

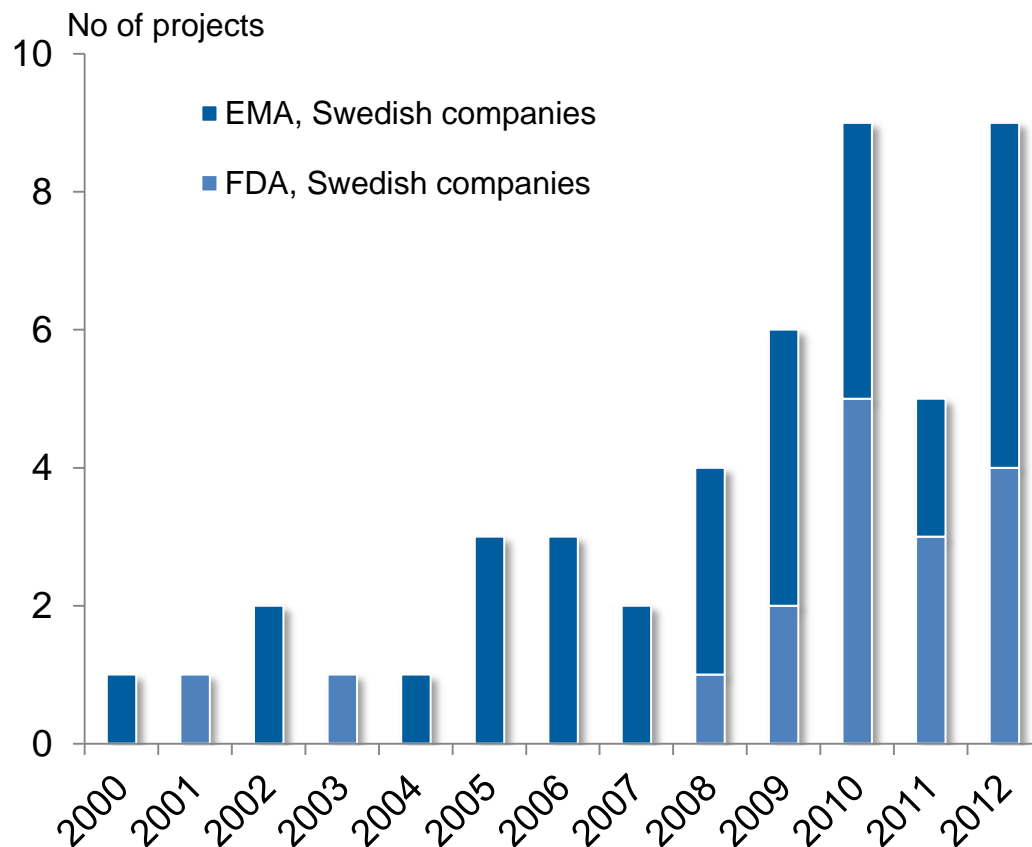
Source: FDA's and EMA's Webpages

Orphan Drug Designations by Swedish companies

Since the year 2000 Swedish companies have received orphan drug designations from EMA and/or FDA for nearly 50 drugs.

- During 2012 the following Swedish companies got orphan drug designations granted from EMA and/or FDA: Albireo, Axcentua Pharmaceuticals, Cortendo and Premacure.

According to answers from the drug development pipeline survey this year, 20% of the projects in Phase I-III are projects intending to apply for orphan drug designation or has already received it (response rate 74%).

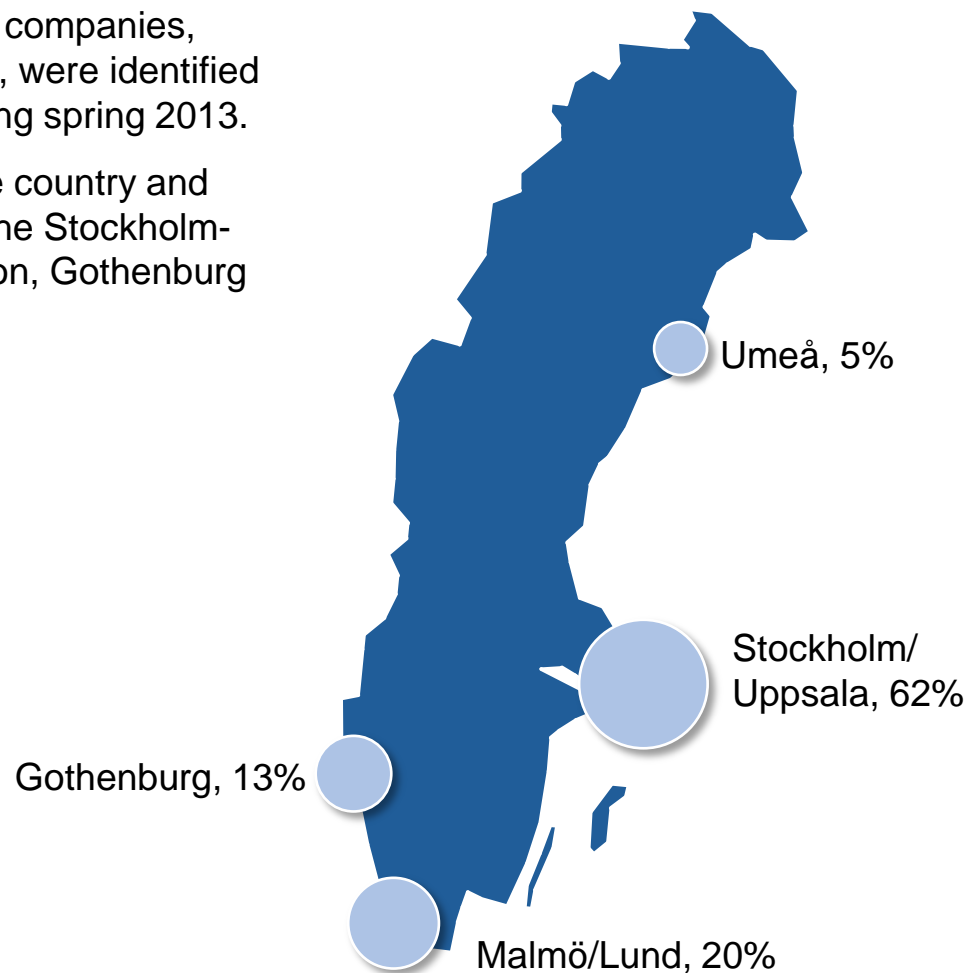


Source: FDAs and EMAs Webpages

4 • Biotech & Pharma Companies with R&D Activities in Sweden

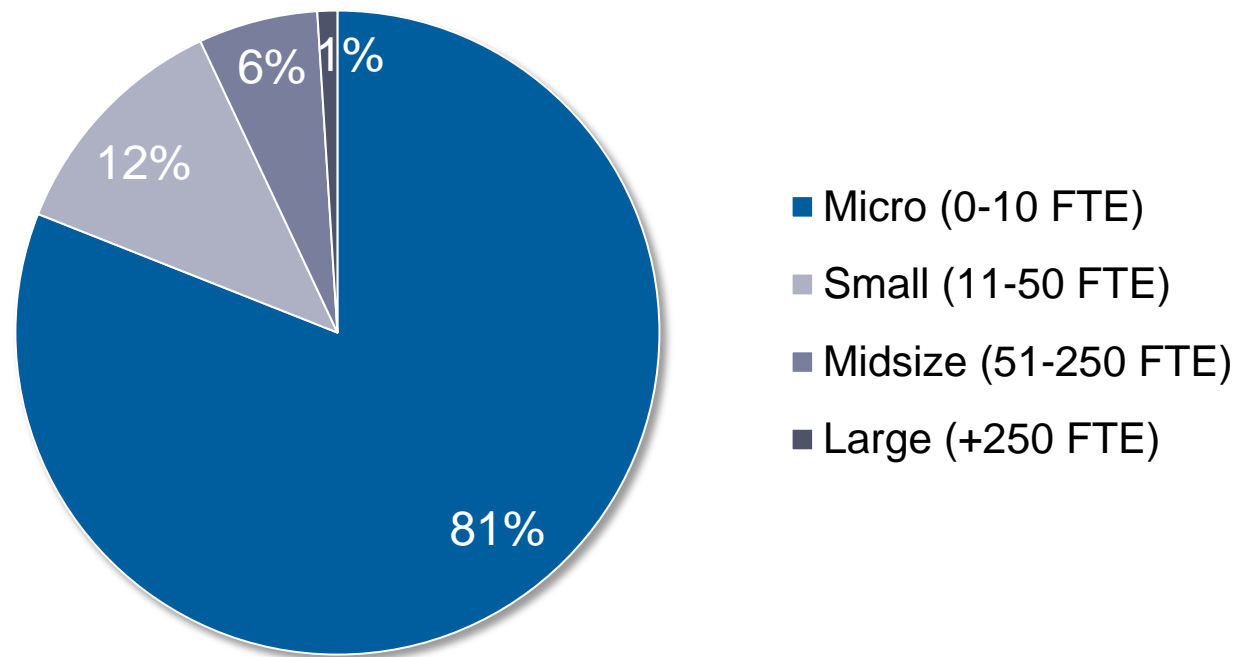
A total of 99 Swedish biotech and pharmaceutical companies, engaged in research and development in Sweden, were identified to be actively working with drug development during spring 2013.

The companies are centered to four regions of the country and the majority of companies (62%) are localized in the Stockholm-Uppsala region, followed by the Malmö-Lund region, Gothenburg and Umeå.



Size of Swedish Biotech & Pharma Companies with R&D Activities in Sweden

Most companies are so called micro-sized companies with 10 or fewer employees (81%). Only one company, Swedish Orphan Biovitrum is large, i.e. with more than 250 employees.



Source: www.allabolag.se. Information is from 2012

Top 10 List of largest companies by Number of Employees

Company	FTE 2012	Turnover 2012 (TSEK)	Head office	Therapeutic area	Founded
Swedish Orphan Biovitrum	514	2 269 030	Stockholm	Rare diseases: inflammation, genetics & metabolism.	1939
Medivir	164	563 929	Stockholm	Infectious diseases: hepatitis C.	1987
Orexo	92	335 929	Uppsala	Specialty pharma and drug delivery technology.	1995
Active Biotech	76	227 908	Lund	Immunology: multiple sclerosis and cancer.	1983
Oasmia Pharmaceutical	71	64 277	Uppsala	Nanoparticle formulations and drug-delivery systems based on well-established cytostatics	1988
Biolnvent International	76	56 406	Lund	Antibody therapeutics: treatment of cancer.	1997
Karo Bio	51	33 224	Stockholm	Nuclear receptors: neuropsychiatry, inflammation, autoimmune diseases and cancer.	1987
Camurus	27	60 335	Lund	Drug-delivery systems for development of high-value therapeutics.	2004
Bioarctic Neuroscience	25	33 233	Stockholm	Neurodegenerative diseases (alzheimer)	2000
Alligator Bioscience	23	15 730	Lund	Immunotherapy of cancer	2000

Source: www.allabolag.se, 2012 Note: Information about Oasmia Pharmaceutical is from 2012-04

Top 10 List of largest companies by Turnover

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Medivir	164	563 929	Stockholm	Infectious diseases: hepatitis C.	1987
Albireo	8	404 755	Göteborg	Gastrointestinal diseases: e.g. chronic constipation and IBS	2007
Orexo	92	335 929	Uppsala	Specialty pharma and drug delivery technology.	1995
Active Biotech	76	227 908	Lund	Immunology: multiple sclerosis and cancer.	1983
Moberg Derma	20	115 187	Stockholm	Skin diseases	2006
Oasmia Pharmaceutical	71	64 277	Uppsala	Nanoparticle formulations and drug-delivery systems based on well-established cytostatics	1988
Camurus	27	60 335	Lund	Drug-delivery systems for development of high-value therapeutics.	2004
Biolnvent International	76	56 406	Lund	Antibody therapeutics: treatment of cancer.	1997
Affibody	17	49 167	Stockholm	Next generation biopharmaceuticals based on its technology platforms.	2004

Source: www.allabolag.se, 2012 Note: Information about Oasmia Pharmaceutical is from 2012-04

Swedish Biotech & Pharma Companies with R&D Activities in Sweden

A1M Pharma	BioInvent International	Hansa Medical	Neurosearch Sweden	Redoxis
Active Biotech	Camurus	Helicure	NeuroVive Pharmaceutical	Respiratorius
AcuCort	Cantargia	Hyron BioMedical	Northern Light Pharmaceuticals	Scandinavian Biopharma
Acure Pharma	Cardoz	Immun System I.M.S.	NovaSaid	Strongbone
Adenovir Pharma	Cebix	Immunicum	Oasmia Pharmaceutical	Swedish Orphan Biovitrum
Affibody	Chemilia	InDex Pharmaceuticals	Omnio Healer Umeå	Synphora
Akinion Pharmaceuticals	ChronTech Pharma	Isifer AB	Oncopeptides	TikoMed
Albireo	ClanoTech	Isofol Medical	Oncorena	Toleranzia
Alligator Bioscience	Cortendo	Kancera	Orexo	Umecrine Cognition
Alzacure	Creative Antibiotics Sweden	Karo Bio	OxThera	Umecrine Mood
Alzinova	DermaGen	KDev Exploratory	Pep-Tonic Medical	Velit Biologics
Anamar	Dextech Medical	KDev Oncology	Pergamum	Vicore Pharma
Apodemus	Diamyd Medical	LIDDS	Pharmalink	WilsonTherapeutics
Aprea	Dilafor	Lipidor	Pharmalundensis	Vivolux
Athera Biotechnologies	Dilaforette	Lipigon Pharmaceuticals	Pharmanest	WntResearch
Axcentua Pharmaceuticals	Duecom Plus-A	Lipoptide	PledPharma	XImmune
Axelar	Edio HealthCare	Medivir	Premacure	2012-12-31
Betagenon	Eurocine Vaccines	Metakalinin	Premune	
Bioarctic Neuroscience	Glactone Pharma	Moberg Derma	Recopharma	
BioChromix Pharma	GliGene	Molecules of Man	Red Glead Discovery	
BioCrine	Glucox Biotech	Neuronova		

Material & Method

The survey investigates drug projects for human use developed by Swedish biotech and pharmaceutical companies. The focus of the survey are finding projects in clinical development, Phase I-III.

Note that a product may be tested for several indications and each indication reported is referred to as a project. Each project may eventually lead to an approval.

Initially, a list of companies with potentially relevant projects was compiled. The list included companies that answered the survey last year and in addition VINNOVA provided a list of drug development companies from their report "Life Science companies in Sweden" (VA 2011:03). Further, regional bio-organizations, science parks, incubators etc. were contacted for information about companies fulfilling the requirements.

Companies on the list were invited to answer the survey (web-based questionnaire) upon invitation by e-mail and subsequent phone calls. SwedenBIO also informed about the survey in a weekly newsletter and on the web site.

In total, 39 companies answered the survey, of which 34 reported projects in Phase I-III. For the remaining companies, pipeline information was collected from company web sites and www.clinicaltrials.gov.

In parallel a company survey was done. Publicdata was obtained from www.allabolag.com. The result from this survey is presented on page 16-20.

AstraZeneca does not divide their research portfolio in different national platforms and as the portfolio alone is approximately the same size as the whole Swedish drug development the pipeline it is shown separately at page 12.

Data from previous years drug development pipeline reports, i.e. -06, -07, -08, -09, -10, -11 and -12 were included for comparison when relevant.

All reports may be downloaded from the website of SwedenBIO: www.swedenbio.com/rapporter.

Contact

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Current and previous pipeline reports may be downloaded from: www.swedenbio.com/rapporter