The Swedish Drug Development Pipeline
June 2012

A survey conducted by:

The Swedish Life Science Industry Organization swedenBIO
VINNOVA
INVEST:SWEDEN

Key findings

- **More companies report clinical trials** – There has been a increase in number of companies contributing with information to the report over the years, indicating that more companies are successful in bringing their projects into the clinic.

- **Size of pipeline** - The Swedish drug development pipeline* is the size of a large international pharma company

- **Cancer, CNS and Infection** – The majority of projects in clinical trials are within the therapeutic area of cancer, CNS and infection.

- **Financing** – The majority of companies stated that financing is the bottleneck to take a project all the way to the market.

*) AstraZeneca is excluded

The survey

- The Swedish Drug Development Pipeline is a survey conducted yearly by SwedenBIO in cooperation with Invest Sweden and VINNOVA dating back to 2006.
- The survey includes projects originating and developed in Sweden and gives a snapshot of ongoing clinical trials among companies answering the survey. Projects originating from AstraZeneca are included in the survey but shown separately* in appendix A.
- The results serve as a quantitative indicator to the progress of Swedish pipeline projects and their characteristics. The results will be used to promote Swedish Drug Development.
- Thanks to all the participating companies!

*) Since AstraZeneca does not divide their research portfolio in different national platforms, their portfolio is shown separately in Appendix A.

Outline

- Survey Details
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- Material and Method

<u>Appendix</u>

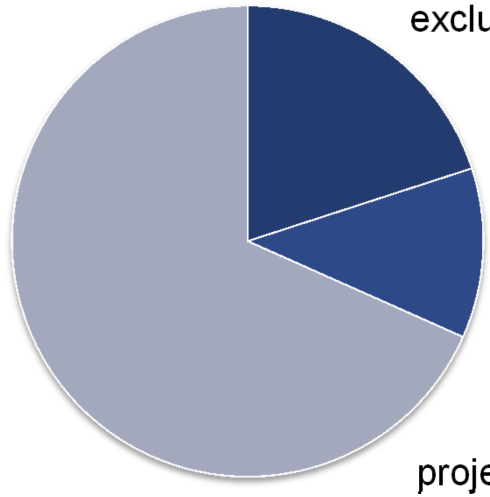
A) AstraZeneca, Drug Development Pipeline 2011

Survey Details

61 companies answered the survey

- 79 companies were contacted about participating in the survey and 61 (77 %) of them responded.
- 12 companies reported projects only in discovery phase or early pre-clinical phase.
- 7 companies reported projects only in late pre-clinical phases.
- 42 companies reported one or more projects in clinical trials (phases I – III).
  - 4 companies that participated last year did not report projects this year due to projects and/ or company sold abroad or closed projects etc.
  - 13 companies that did not report projects last year stated projects this year.

Response to the survey, (n=61)

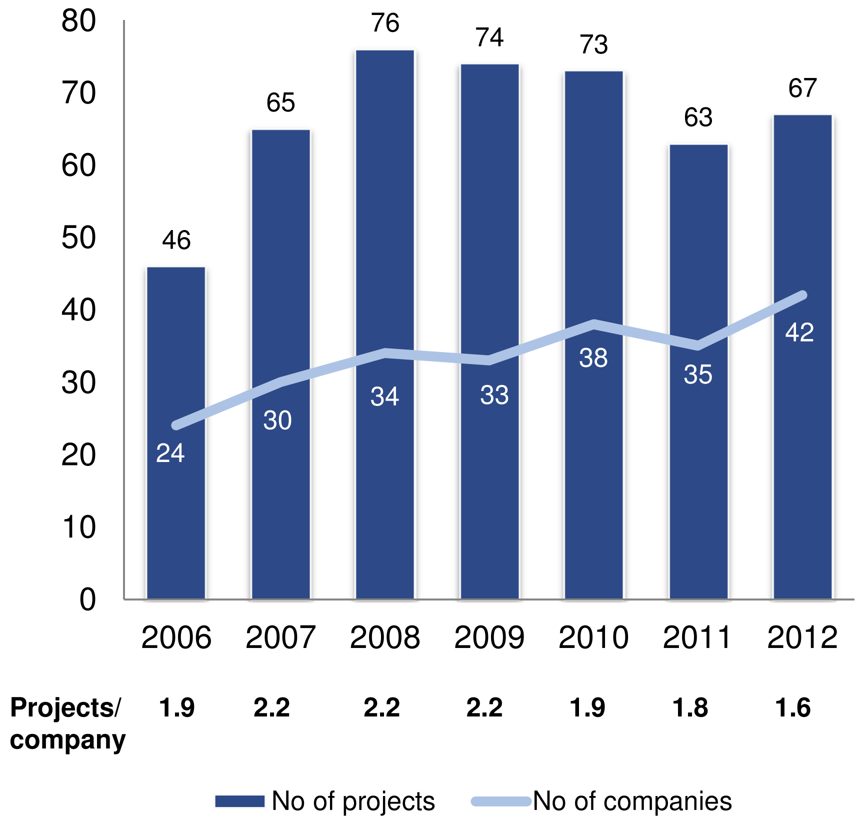


Overview of Number of Projects and Companies

More companies enter clinical trials

- There has been a increase in number of companies stating projects in clinical trials over the years, from 24 in 2006 to 42 in 2012.
- This year 42 companies reported 67 projects in clinical trials.
  - 16 of the projects stated last year are not included this year due to closed results, projects sold abroad etc.
  - 24 new projects were reported this year.
- The average of projects per company is just below 2, with a downward trend.

42 companies stated 67 projects in phase I – III

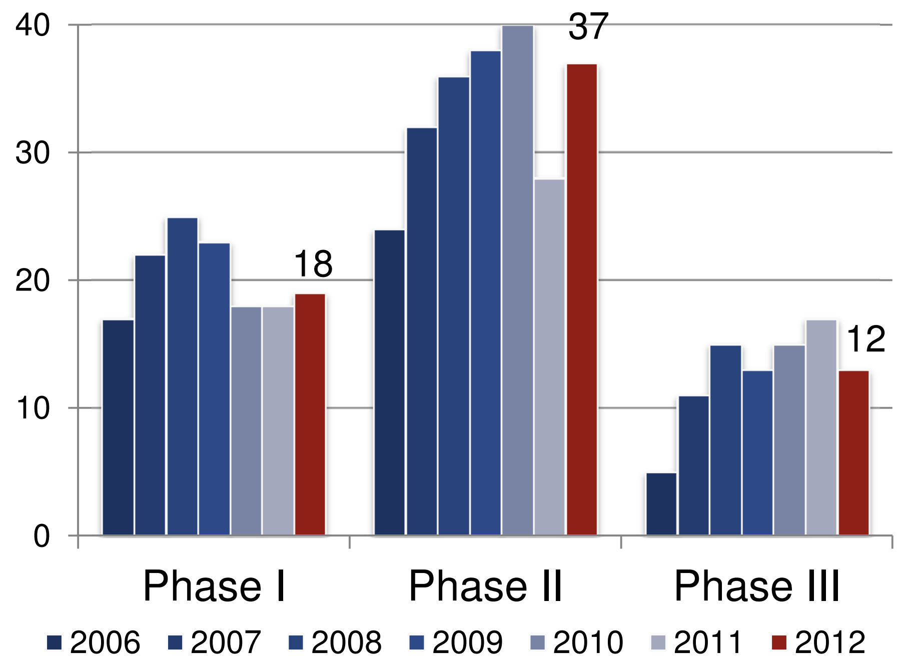


Distribution of Projects in Clinical Trials

Most projects are in phase II

- Of the companies that stated projects in phase I – III last year, the majority of projects are still in the same phase.
- The majority of reported projects are in clinical phase II.
- Three of the projects that were reported in phase I last year has entered phase II.

The graph shows an overview of projects in phases I – III.



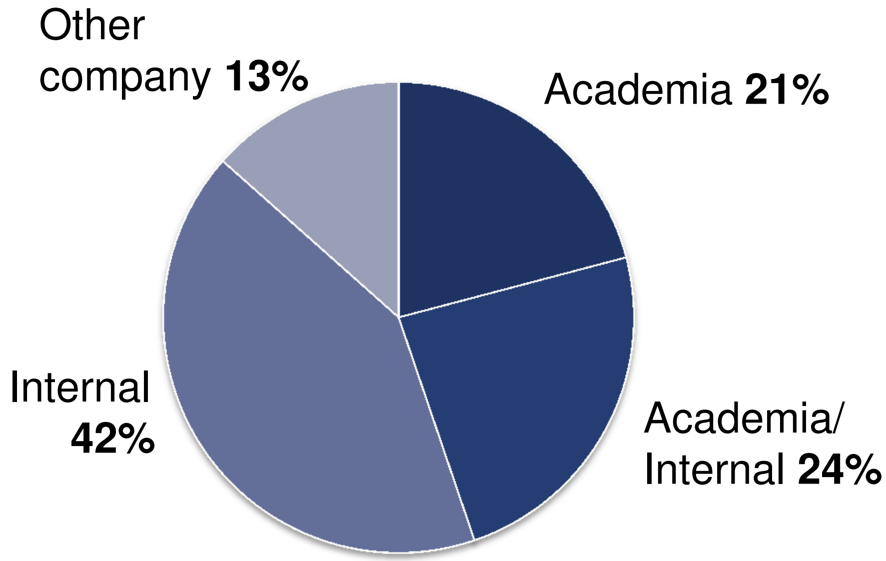
*) Besides this years report, data included comes from previous Drug Development Pipeline reports.

Origin of Project

Most projects originate from internal research, or from collaborations with academia

- Most projects originate from internal research, or from collaborations with academia. This finding is similar to last years.
- 45 % of the projects in clinical trials originate at least in part from academia. Reasons for this may be:
  - Strong collaborative ties industry-academia
  - Companies have been founded around projects

Origin of projects in clinical trials, (n=67)

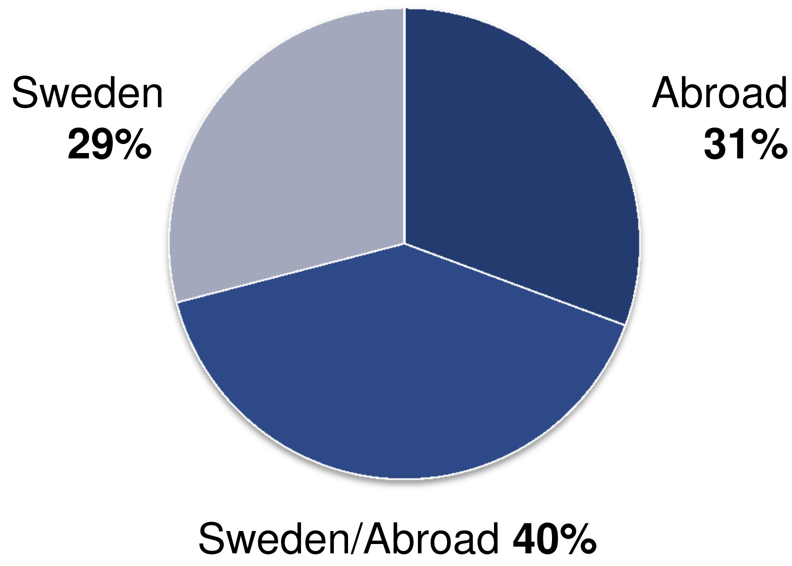


Location of Clinical Trials

Swedish patients are included in a majority of the clinical trials

- Swedish patients are included in a majority of the clinical trials, phase I -III . This result is similar to last years report.
- Of the 12 projects in phase III, 8 are tested in clinics both in Sweden and abroad, 4 abroad only. No company reported phase III trials in Sweden only.

Overview of location of clinical trials, (n=67)



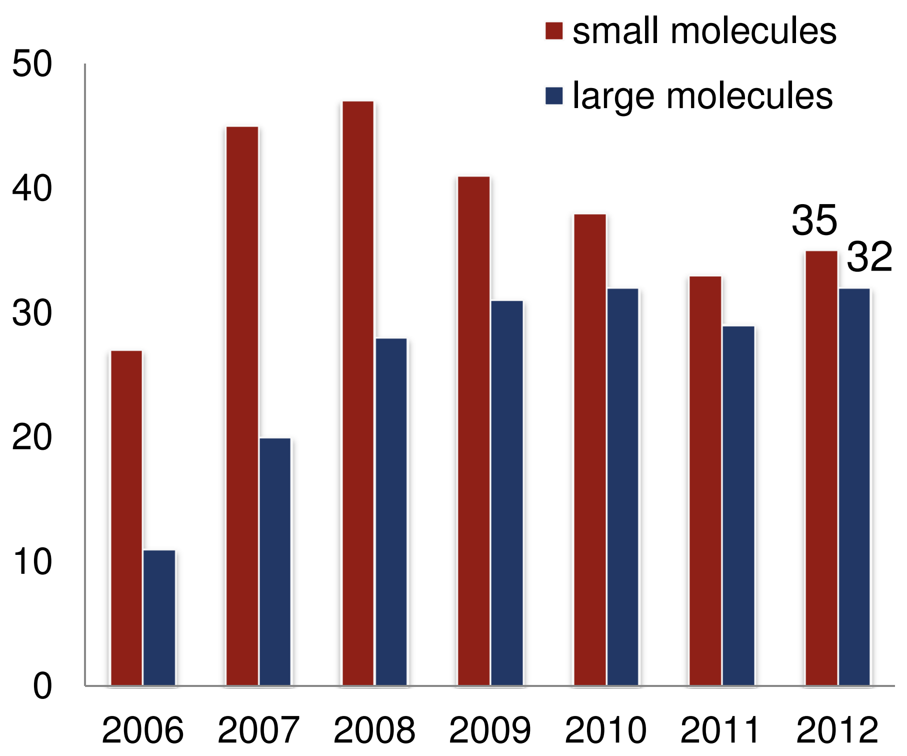
Small and Large Molecules

Small, chemically manufactured molecules make up the majority of drugs on the market today. Large molecules, also known as biologics (protein-bases molecules) are getting increased attention due to the great potential they have for diseases that currently are untreatable.

Half of the projects in the Swedish drug development pipeline are large molecules

- Out of the 67 projects reported in clinical trials, 35 are small molecules and 32 are large molecules.
- Over the past years the number of small molecules in clinical trials have decreased while the number of large molecules have increased.

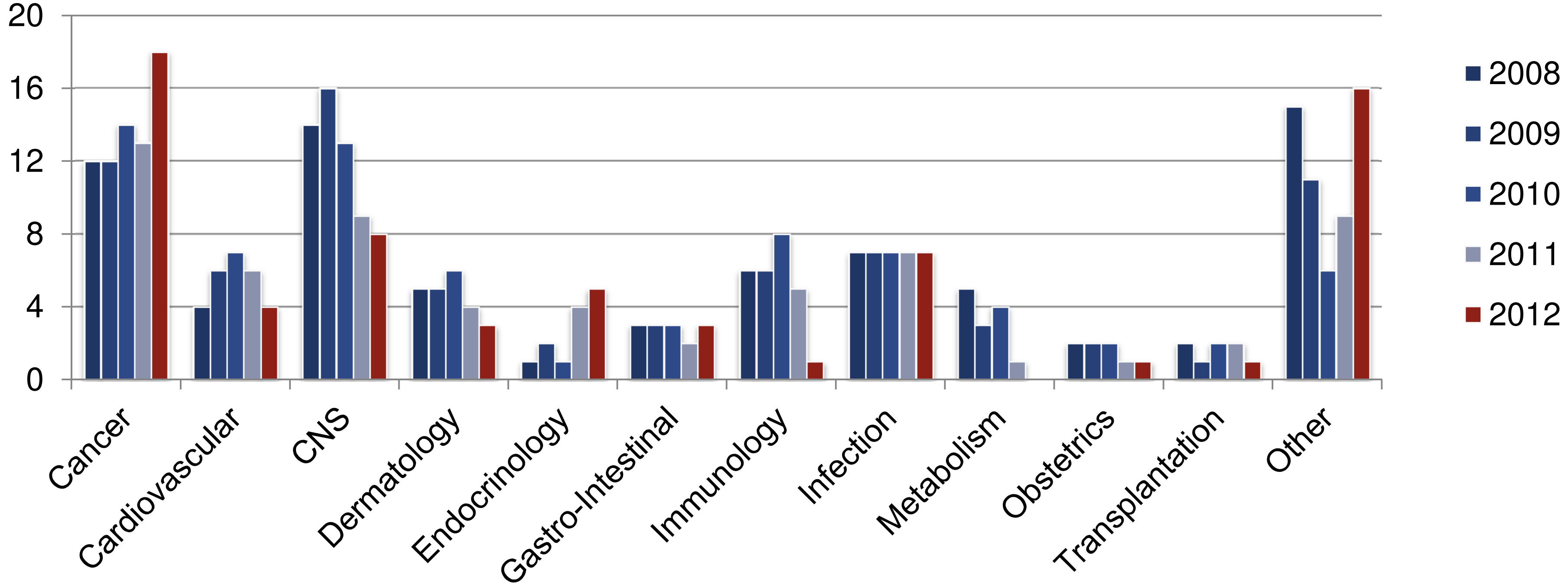
The graph shows an overview* of small and large molecules in clinical trials.



*) Besides this years report, data included comes from all previous Drug Development Pipeline reports.

Projects in Phases I - III by Therapeutic Area

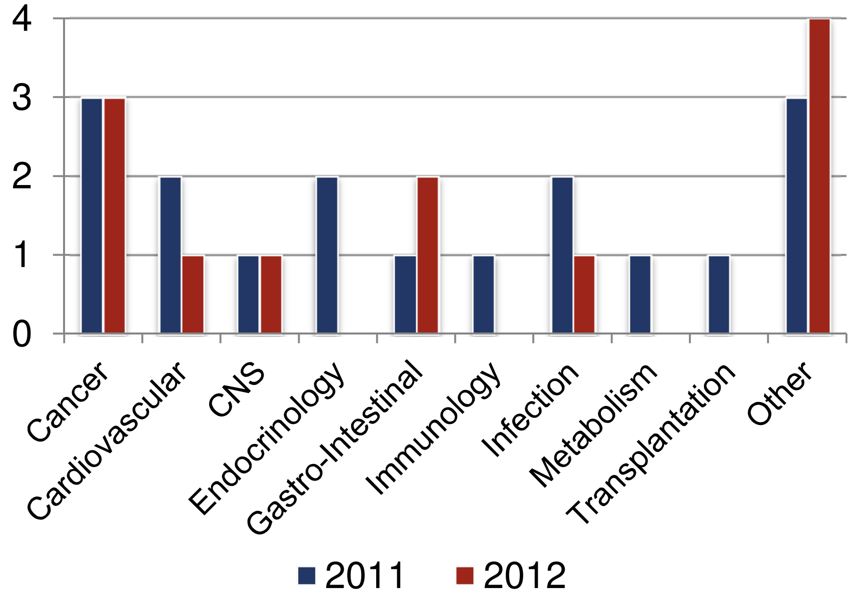
- Cancer is the therapeutic area with most projects, followed by CNS and infection.
- The category "Other" include projects in e.g. pain, osteoporosis and projects with undisclosed therapeutic area.



Projects in Phase III by Therapeutic Area and Approved Products 2011

The majority of projects reported to be in clinical trials phase III last year remains there

- Two new projects were reported in phase III, one gastro-intestinal project and one with undisclosed therapeutic area.



Three products were approved during 2011

- Orexos cancer pain treatment Abstral was approved in both USA and Canada (2011-01).
- DuoCort Pharma's orphan drug Plenadren granted European marketing authorization for adrenal insufficiency (2011-11).
- Camurus received 510(k) clearance from the FDA to market Episil in the US for management and relief of oral pain for cancer patients suffering from oral mucositis (2011-09).

Material and Method

- A list of companies with potentially relevant projects (projects originating and developed in Sweden) 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).
- Companies on the list were encouraged to respond to the survey (web-based questionnaire) upon invitation by e-mail (sent out end of May) and subsequent phone calls. SwedenBIO also encouraged companies to participate by information about the survey in their weekly newsletter.
- Note that due to mergers, acquisitions, liquidations and other explanations, a certain proportion of companies participating in the survey differs from year to year (see pages 5 and 6).

Comments

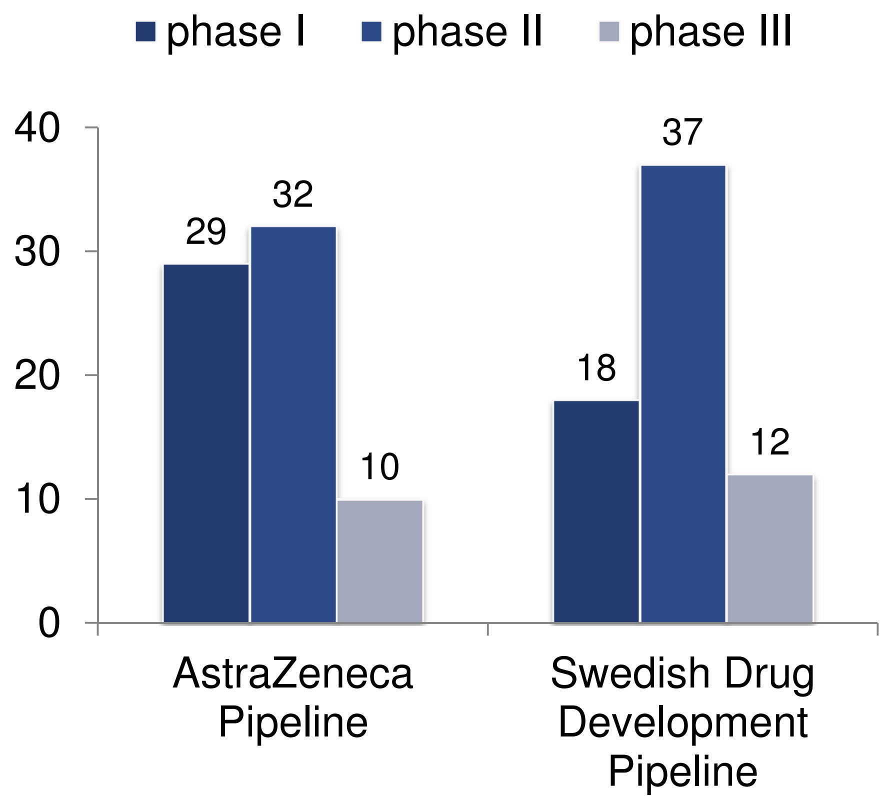
- Data from previous years comes from the SwedenBIO Drug Development Pipeline Report from -06, -07, -08, -09 , -10 and -11. The reports can be downloaded from the website of SwedenBIO (www.swedenbio.com/rapporter).
- Since AstraZeneca does not divide their research portfolio in different national platforms, their portfolio alone represents approximately the same size as the whole Swedish drug development pipeline and is thus shown separately (see Appendix A).

AstraZeneca, Drug Development Pipeline 2011

Due to that AstraZeneca does not divide their research portfolio in different national platforms, the projects are presented separately.

Summary

- Globally, AstraZeneca reported 63 projects in phases I – III during 2011, as compared with the 67 projects listed in this year's Swedish Drug Development Pipeline Report.
- Most projects are in the therapeutic area of cancer and respiratory/inflammation.
- AstraZeneca reported an additional 23 products in clinical trials that are line extensions.



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