

Understanding and Choosing Your Partner: Big Pharma, MidPharma, or Biotech?

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Specialist strategy consulting firm for life sciences companies
One Nucleus Life Science Leadership Series
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- Introduction to Novasecta
- European MidPharma landscape
- Oncology Partnerships



Specialist pharma/biotech strategy consultants working exclusively with CEOs, R&D heads and senior commercial leaders



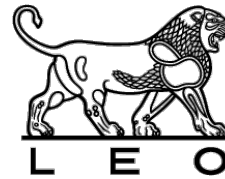
Deliver performance improvement through deep strategic and operational knowledge across the entire pharmaceutical value chain



A highly experienced team of senior consultants lead the development and embedding of experience-based solutions that stick

Novasecta works exclusively with pharma/biotech CEOs, R&D heads and senior commercial leaders

A Selection of Novasecta's Clients over the Last Five Years



Novasecta delivers performance improvement through strategies, capabilities and partnerships



Strategies

Frame, develop and implement value-adding corporate, commercial and R&D strategies



Capabilities

Identify, develop and embed distinctive organisational capabilities



Partnerships

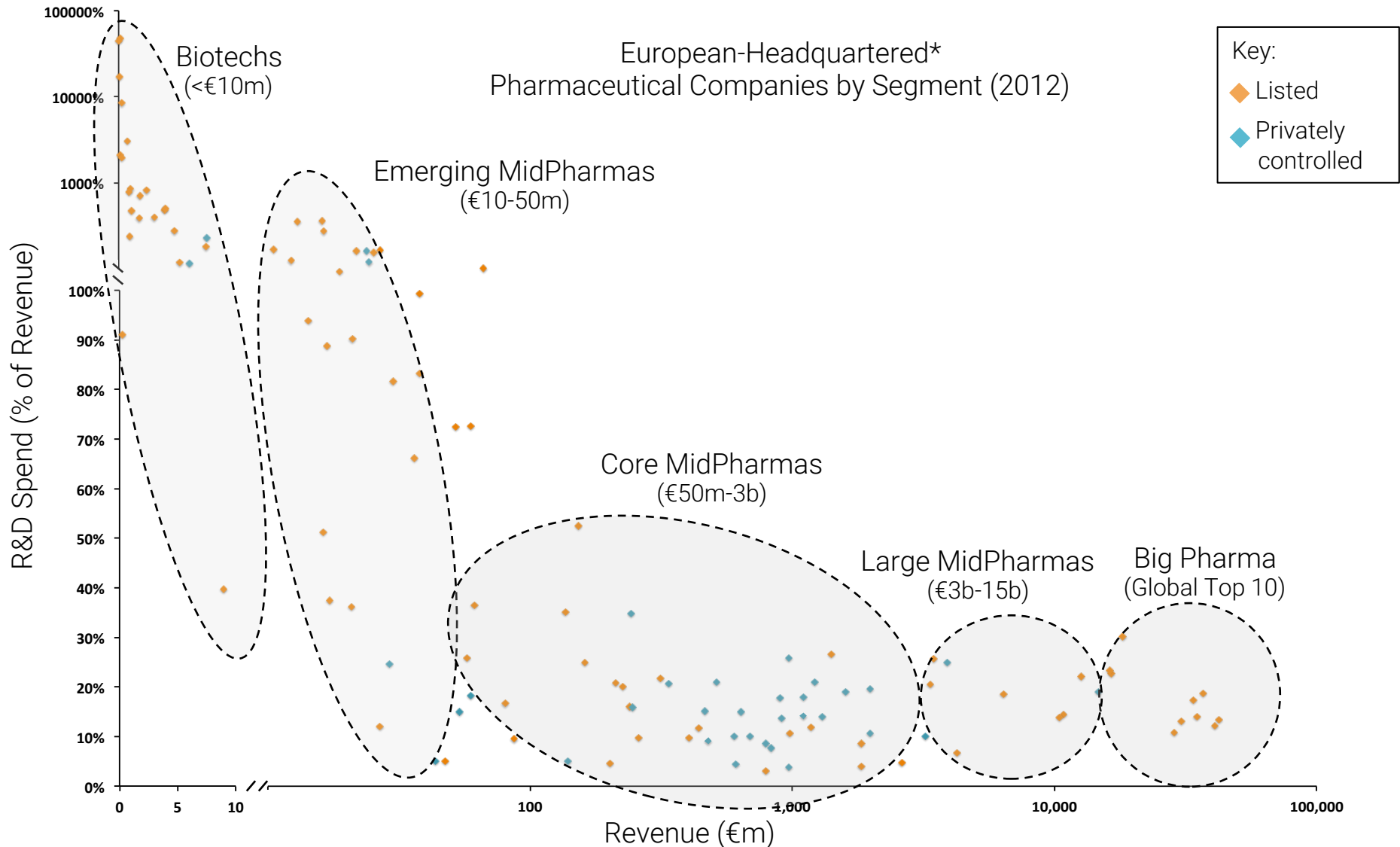
Source, profile and create structures for corporate, commercial and R&D partnerships

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The European pharmaceutical landscape is highly diverse



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Note: *EU-headquartered companies with exception of global top 10 Big Pharma.
 All figures for calendar year 2012 or earlier to 2009 if not available, excludes companies where R&D investment not disclosed.

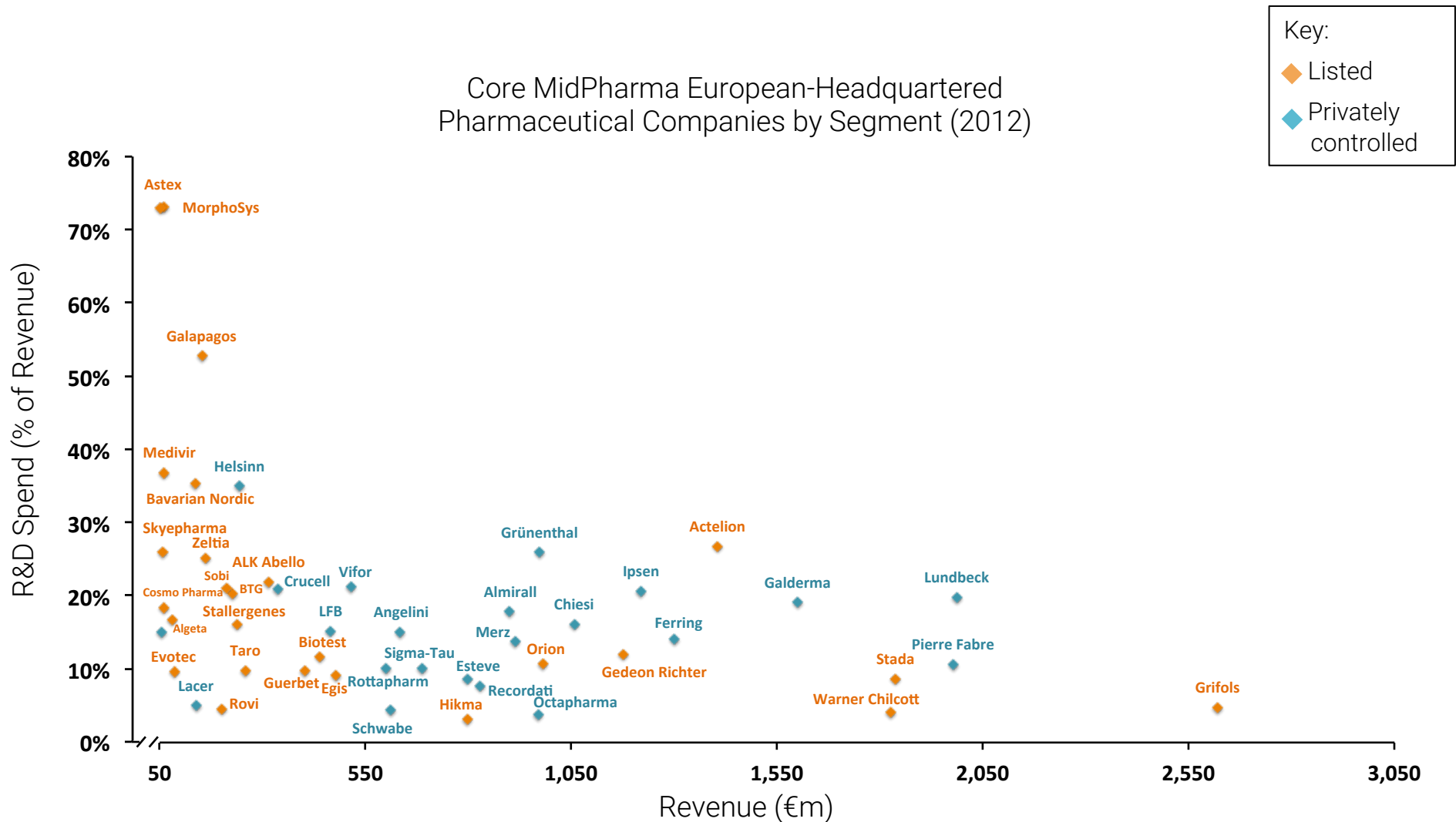
Source: Novasecta analysis of public domain data from company websites, annual reports.

A large number of Core MidPharmas are privately owned or controlled



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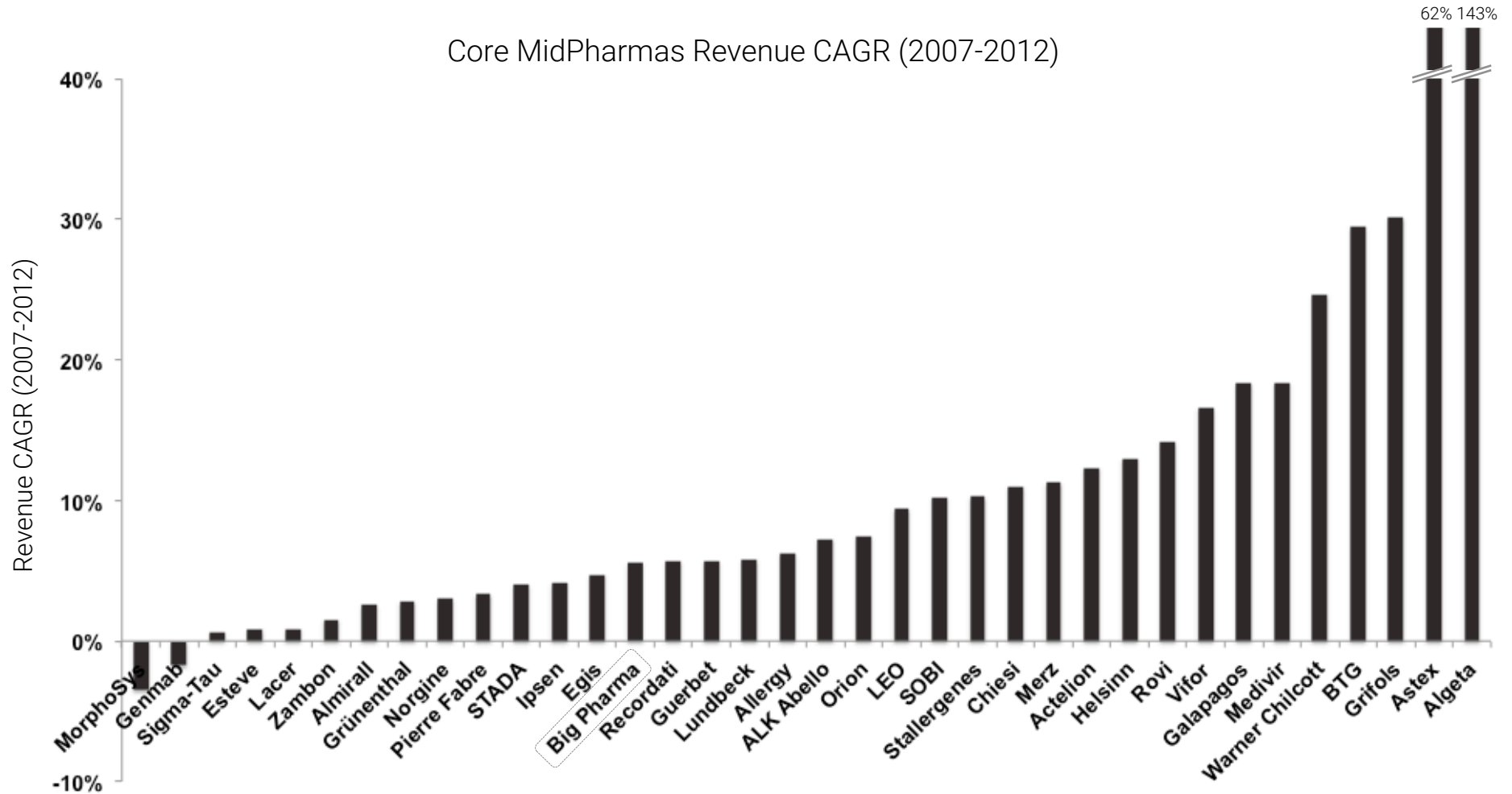
Core MidPharma European-Headquartered
Pharmaceutical Companies by Segment (2012)



Source: Novasecta analysis of public domain data from company websites, annual reports.

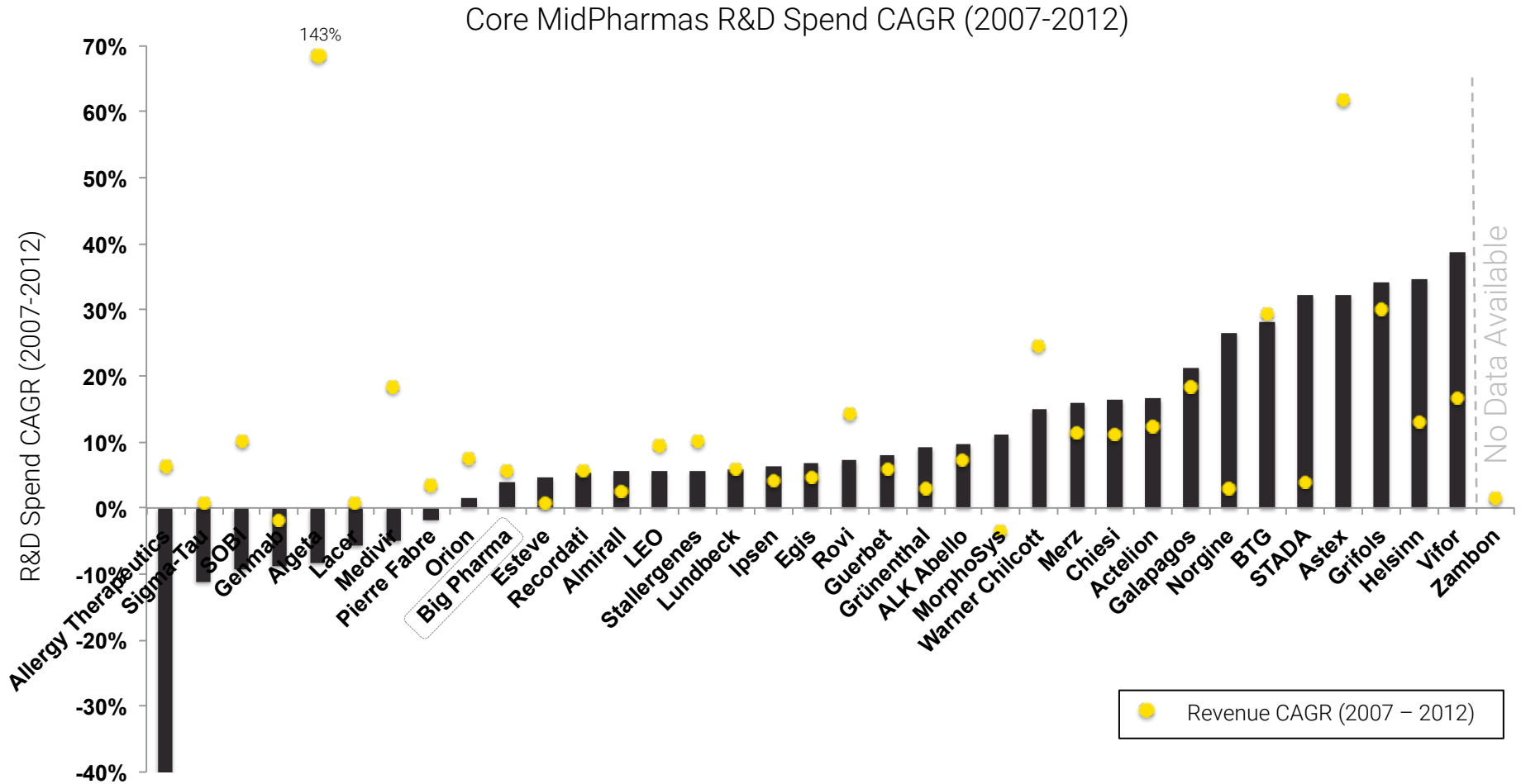
Note: *Menarini and Takeda will fall within the Large MidPharma category. All figures for calendar year 2012 or earlier to 2009 if not available, excludes companies where R&D investment not disclosed.

Many Core MidPharmas have shown strong revenue growth over the last five years



Source: Novasecta analysis of public domain data from company websites, annual reports. Big Pharma defined as top 10 companies by revenue globally. Core MidPharmas defined as €50m - €3bn revenue. Norgine data is 2007 - 2011 CAGR, Algeta is 2008 - 2012 CAGR (no revenue reported in 2007).

About 35% of Core MidPharmas also grew their R&D investments faster than they grew revenue over the last five years



Source:

Novasecta analysis of public domain data from company websites, annual reports. Big Pharma defined as top 10 companies by revenue globally. Core MidPharmas defined as €50m - €3b revenue. Sigma-Tau data is 2007 – 2011 CAGR, Algeta is 2007 – 2011 CAGR (no revenue reported in 2007), Norgine is 2007 – 2009 CAGR, Helsinn is 2007 – 2011 CAGR.

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Oncology was a high-stakes area for partnerships for players of all sizes in the last year

Top five disclosed deals* in oncology in 2013-Feb 2014



- Ablynx and Merck in discovery and development agreement for nanobodies for cancer immunotherapy (Feb 2014)
 - €20m upfront + €10.7m in research funding over three years. Ultimate potential of around €1.7b plus tiered royalties.



- Oncomed and Celgene sign collaboration to develop and commercialise up to six anti-cancer stem cell products from Oncomed's pipeline (Dec 2013)
 - €116m upfront + Celgene will purchase approx. \$17m shares. Additional payments will be made for development, regulatory and commercial milestones on a per program basis.



- Roche enters research collaboration with Molecular Partners AG for DARP-in drug conjugates for cancer (Dec 2013)
 - €44m upfront + research funding and up to €800m if all development and sales milestones are met.



- Roche signs development and commercialisation agreement with Immatix for multiple cancer vaccines and therapeutics (Nov 2013)
 - €13m upfront + committed research funding and potential milestone payments in excess of €750m.



- MorphoSys and Celgene create strategic alliance to advance anti-cancer antibody for multiple myeloma (June 2013)
 - €71m upfront + Celgene will invest €46m for new shares of MorphSys AG with a total value of up to €628m

It also received a number of high profile early stage investments



- Juno Therapeutics launched with \$120m in venture financing (Feb 2013)
 - Company will focus on cancer immunotherapy, using technologies developed at the Fred Hutchinson Cancer Research Centre, Seattle; Children's Research Institute; and Memorial Sloan-Kettering Cancer Centre, New York.
 - Investors include Arch Venture Partners and the Alaska Permanent Fund.
 - Note: Juno expanded its Series A venture financing to \$145m through additional investments from Bezos Expeditions and Venrock Partners in Jan 2014.



- Jounce Therapeutics launched with \$47m in venture financing (Feb 2013)
 - Company will focus a pipeline of antibodies and other injectable protein drugs that can spark the immune system to fight cancer.
 - Investors include Third Rock Ventures.

Diverse motivations influence the ideal type of partner(s) for a Biotech, MidPharma or Big Pharma

		Partner Type					
		Academia	Biotechs	MidPharma	Big Pharma		
Commercialisation	Development	Discovery	Innovation	✓	✓	✓	
		Risk share		✓	✓	✓	
		Spare P&L		✓			
	Efficiency		✓				
	Financing			✓	✓		
	Therapy area knowledge and/or market access			✓	✓		
	Access to geographies / local network			✓	✓		

In 2013, many oncology deals involved Biotechs seeking funding for discovery assets and technologies

Partnership Types of Key Oncology Deals in 2013			
Phase at Signing	Biotech & MidPharma	MidPharma & MidPharma	Big Pharma & Biotech
Discovery	Diaxonhit / Boehringer-Ingelheim novel splice variants		Merck (MSD) / Ablynx nanobody cancer immunotherapies
	Champions Oncology / Teva TumourGraft platform		Roche / Molecular Partners DARPin-drug conjugates
Development	bluebird bio / Celgene gene therapy for chimeric antigen receptor (CAR) T-cells	Roche / Immatics cancer vaccines, immunotherapies	
	OncoMed / Celgene anti-cancer stem cells	Amgen / Astellas 4 biologics, 1 small molecule for oncology, CVS, bone in Japan	
		Morphosys / Celgene antibody for multiple myeloma	

Biotechs are partnering with MidPharmas and Big Pharma, but MidPharmas are also partnering with each other

MorphoSys & Celgene's strategic alliance demonstrates a more strategic approach than the classic early-stage license

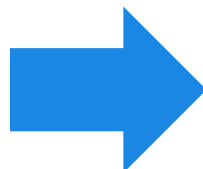


- Joint development of a novel therapeutic antibody for multiple myeloma
- Celgene secured worldwide rights to MOR202
- MorphoSys received upfront payment of €70.8 million (US \$92m)
 - Celgene also invested €46.2m (US \$60m) in new shares for MorphoSys
- Both companies will jointly develop MOR202 globally and co-promote in Europe
- MorphoSys retained 50/50 profit sharing in its co-promotion territory and is eligible to receive tiered double-digit royalties outside the co-promotion territory
- Deal was struck during phase I/IIa trial in patients with relapsed/refractory myeloma

"This alliance takes MorphoSys to the next stage of our corporate development. By moving up the value chain we have the opportunity to develop a commercial organization that expands on our significant research, development and technology expertise of today."
– Dr. Simon Moroney, CEO MorphoSys

More unusually, Biotechs can also be partners for progressing MidPharmas' oncology assets

- In January 2009, Wilex licensed UCB's entire preclinical oncology portfolio comprising two small molecule and three antibody programs.



- Deal terms:
 - UCB will receive milestone and royalty payments from Wilex.
- Option to reacquire:
 - UCB retains an exclusive option to reacquire each program, in this case, milestones and royalties will flow in the opposite direction- from UCB to Wilex.
- Equity investment:
 - In addition, UCB will invest €10 million in WILEX for a 13% stake
 - UCB will also make milestone payments of €10 million in total upon application of clinical Phase 1 trial and first dose in man.
- “This alliance will give UCB the opportunity to focus our R&D priorities in our core indication areas, central nervous system and immunology” - Dr Melanie Lee, Executive Vice-President UCB and President UCB New Medicines.

- Partnership has progressed: In July 2013, UCB acquired back non-oncology rights to one lead program and paid Wilex undisclosed amount with commitment to future development milestones and royalties.

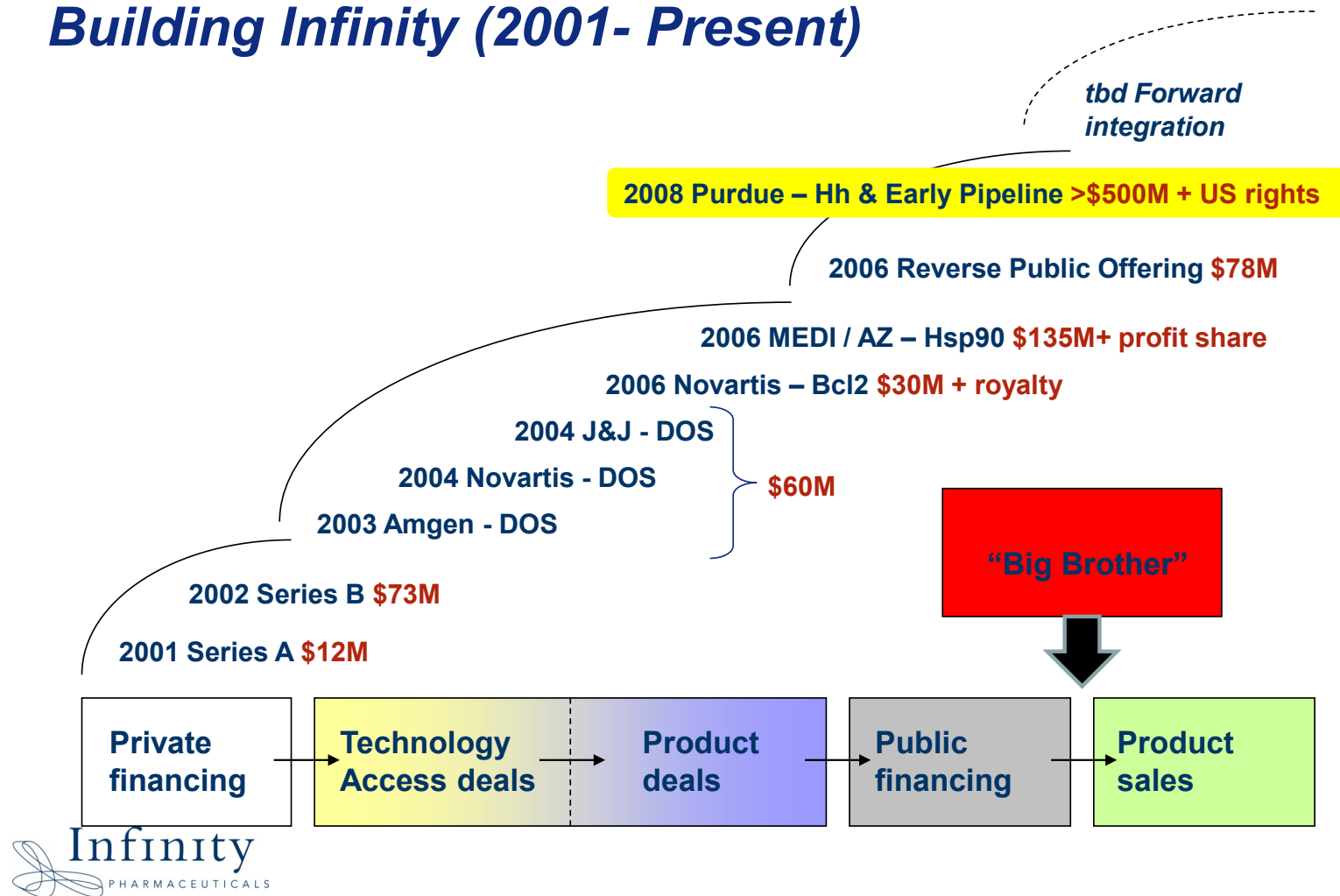
Sadly oncology deals also have terminations: in 2013 these were typically due to data and/or changes in corporate strategy

Partnership	Deal Summary	Reason for Deal Termination
Teva – CureTech	<ul style="list-style-type: none"> • Antibody for PD-1, B7 receptor. • Signed 2006 in Phase I, \$6m upfront + \$23m option. 	<p>Feb 2013 “No longer a priority for Teva’s R&D program, largely because the field is so crowded and also because Teva’s strengths lay elsewhere”.</p>
BMS – Lilly	<ul style="list-style-type: none"> • Necitumab (next gen. Erbitux) for non-small cell lung cancer. • Initially developed by ImClone, won by Lilly in 2010 in rights battle with BMS. 	<p>Feb 2013 “Reprioritisation of BMS development portfolio”, although a Phase III trial had previously been dropped due to safety concerns.</p>
ArQule – Daiichi Sankyo	<ul style="list-style-type: none"> • Kinase inhibitor. • Signed 2011 at Phase I, \$10m upfront plus Phase I, \$255 milestones. 	<p>Apr 2013 Lost of confidence due to Phase III disappointing data in another compound (tivantinib) between the two companies.</p>
Teva – Rexahan	<ul style="list-style-type: none"> • Signed 2009. • Upfront \$3.5m plus investments to 6.3% equity stakes by July 2013. 	<p>Aug 2013 “No longer fits Teva’s oncology strategy”.</p>

How to ensure long lasting partnerships?

Infinity Pharmaceuticals demonstrates how partnering preferences change with time, for example from Big to Mid-sized

Building Infinity (2001- Present)



Source: Steven Holtzman, former CEO, partnering presentation (2012)


Astex also started partnering with Big Pharmas before merging with a MidPharma then being acquired by another MidPharma

- Astex Therapeutics was established in 1999.
- Initial discovery deals almost entirely with Big Pharmas.
- Merged with US MidPharma Supergen, Inc. and renamed to Astex Pharmaceuticals in September 2011:
 - Supergen had ongoing revenues through one marketed product, Dacogen® (anti-cancer).
- Acquisition by MidPharma Otsuka completed in October 2013.

Astex's Pipeline 2012: Dominated by Big Pharma Partnerships

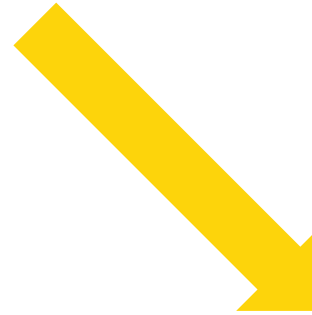
Partnered Products and Programs

Astex's partners are advancing several Astex compounds in clinical trials. These trials are completely funded and executed by our partners.

Compound Name / Mechanism	Discovery	Preclinical	Phase 1	Phase 2	Partner
LEE011 – CDK4 inhibitor (Oncology)	▶				
AZD5363 – PKB/Akt inhibitor (Oncology)	▶				
JNJ42756493 - FGFR inhibitor (Oncology)	▶				
AZD3293 – BACE inhibitor (Alzheimer's)	▶				
Multiple targets (Multiple therapeutic areas)	▶ Discovery milestones achieved				

In summary, commitment by all parties is the foundation to long-term partnering success, a quality that distinguishes MidPharmas

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		Spare P&L		✓		
	Development	Efficiency		✓		
		Financing			✓	✓
		Therapy area knowledge and/or market access			✓	✓
		Access to geographies / local network			✓	✓



	Pros	Cons
Big Pharma	<ul style="list-style-type: none"> Instant credibility by public markets Deep pockets 	<ul style="list-style-type: none"> Change in strategy Change in people
Mid Pharma	<ul style="list-style-type: none"> Dedication to assets Flexible financing 	<ul style="list-style-type: none"> Less credibility by investors
Biotech	<ul style="list-style-type: none"> Access to technology/ innovation 	<ul style="list-style-type: none"> Little financing