



BENTAIEB Fathi  
FETRO Christine  
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MAAMAR Suina  
RAME Blandine

Jan. 29th, 2014  
M2 AREIPS





# Summary

1. History
2. Celgene ID
3. Celgene's strategy
4. Perspectives
5. Conclusion - SWOT

# 1 – HISTORY





# History



Fine and specialty  
chemicals  
man made fibers



Separate  
enterprise Celgene  
Corporation

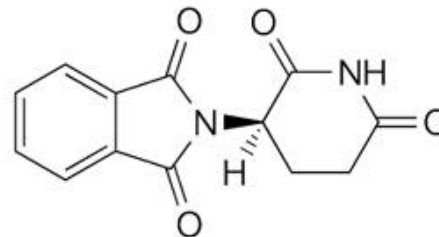
- Biological work
- Isomeric drug (Ritaline, Thalidomide)



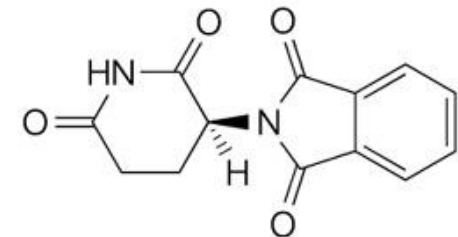
# Thalidomide

- First patent in 1954 by Grünenthal
  - Placed on the market on October 1957 (Germany)
- effective tranquilizer and pain killer  
-effective antiemetic

a synthetic glutamic acid derivative



*R*-(+)-Thalidomide



*S*-(-)-Thalidomide

# Thalidomide's teratogenic effects

Congenital abnormalities caused by use of thalidomide in pregnancy:  
On Nov 21, 1961, the company withdrew thalidomide from sale in Germany

only one particular optical isomer  
of thalidomide caused the teratogenicity

⇒ Conversion in the human body

Withdrawn from the market in 1962 except in  
South America





# At the beginning, Celgene and Thalidomide ...

- 1991: Gilla Kaplan has a better project for the company ... (other than tuberculosis)
- new research showed thalidomide could treat the painful skin lesions caused by leprosy (and AIDS+ cancer)

Celgene's 1992 acquisition of exclusive US rights for thalidomide

- A very worthwhile project
- A tremendous challenge working with the FDA



# Leprosy-ENL

- a *Mycobacterium leprae* infection
- a diffuse, generalized pattern with **clusters of tender**, swollen subcutaneous **nodules** over the face, trunk, thighs, and arms

⇒ Immune-mediated complication

⇒ July 1998: approval from the FDA to market for the acute treatment of the cutaneous manifestations of moderate to severe ENL

APPROVED







APPROVED

## Antitumor Activity of Thalidomide in Refractory Multiple Myeloma

Seema Singhal, M.D., Jayesh Mehta, M.D., Raman Desikan, M.D., Dan Ayers, M.S., Paula Roberson, Ph.D., Paul Eddlemon, B.S., Nikhil Munshi, M.D., Elias Anaissie, M.D., Carla Wilson, M.D., Ph.D., Madhav Dhodapkar, M.D., Jerome Zeldis, M.D., David Siegel, M.D., Ph.D., John Crowley, Ph.D., and Bart Barlogie, M.D., Ph.D.

N Engl J Med 1999; 341:1565-1571

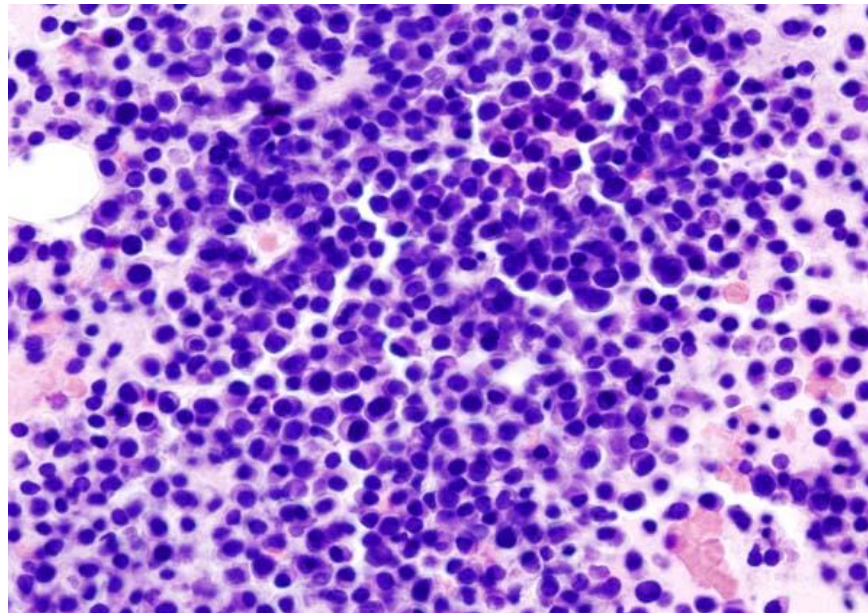
- May 2006: approval in combination with dexamethasone for the treatment of patients with newly diagnosed multiple myeloma

# Multiple myeloma

A cancer formed by  
malignant plasma cells

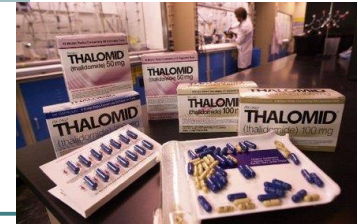
C R A B

- 1.22/10000 in the UE
- About 20 000 cases occur every year in the USA





# Thalidomide Celgene® an incredible story ...

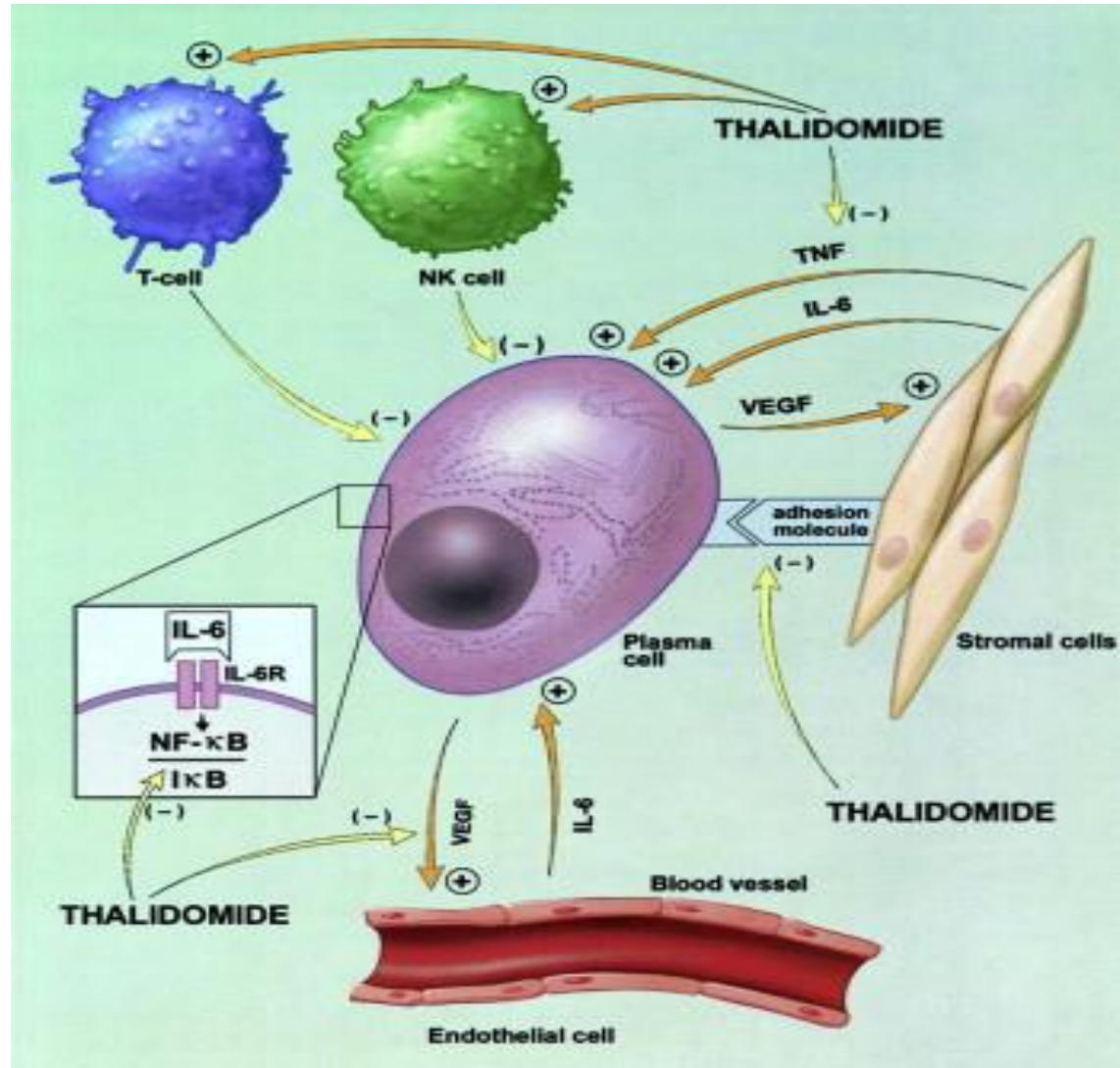


*“There has never been a drug that has so profoundly affected drug development around the world as has Thalidomide”* Sol Barer, Chief executive officer, manufacturer Celgene Corporation. JAMA 1997 : 8-10

- *Designated as an **orphan medicinal** product by the European Commission in 2001*
- *Sales:*
  - *In 1998 : 3,3 millions \$*
  - *In 2001 : 82 millions \$ = 93 % of Celgene’s total revenue*
- *Using as a springboard to build a **pipeline of drugs** whose chemical structures were derived from thalidomide = IMiDs*

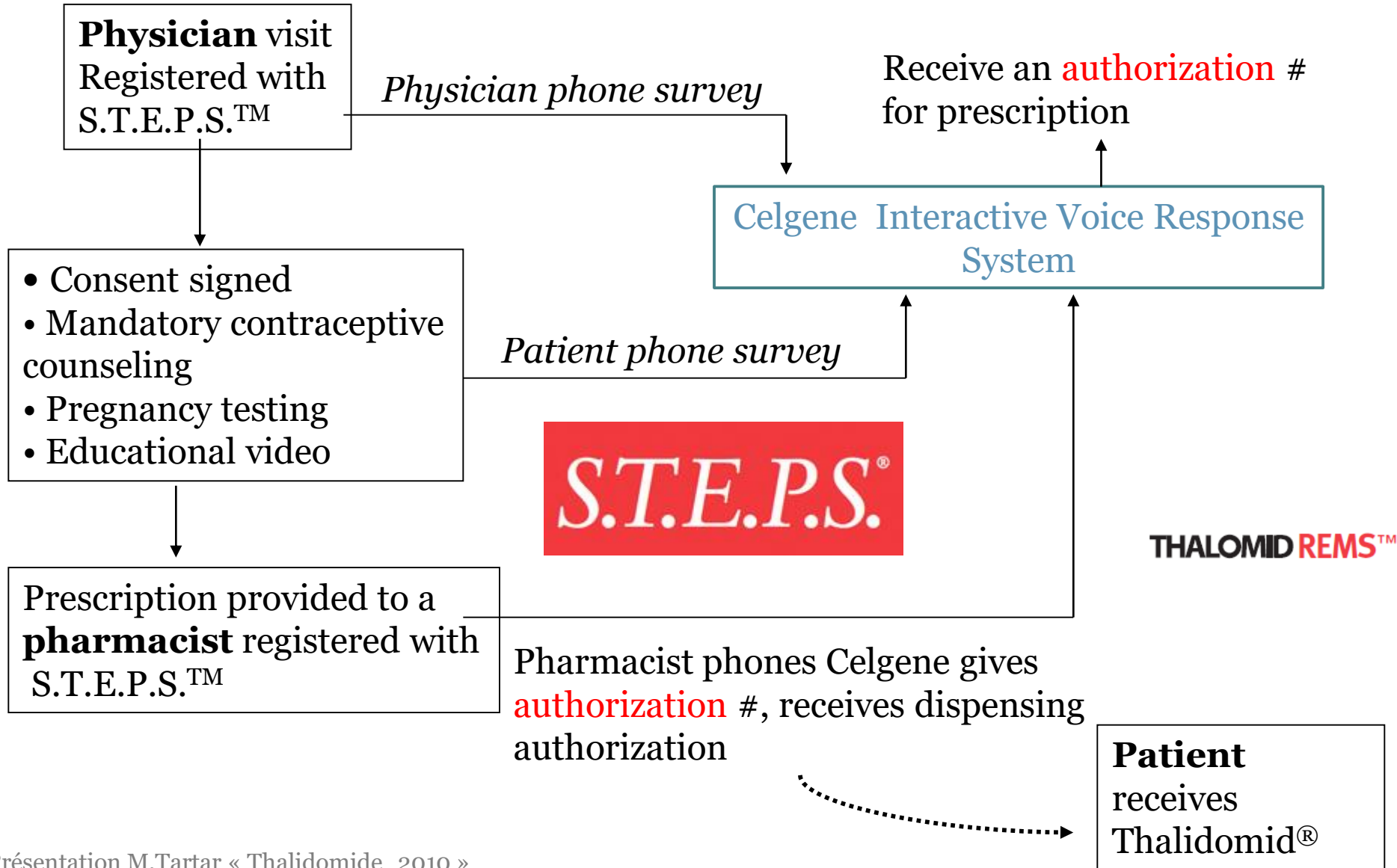


# Why we can use Thalidomide ?





# The System for Thalidomide Education and Prescribing Safety



## 2 – IID CELGENE







# 2-1 Origin of Celgene

- Biopharmaceutical laboratory specializing in innovation
- Since 1986

Celgene Corporation



- New Jersey

Headquarters



- Set up in 50 countries
- Patients in 70 countries

In the World



- Hematology
- Oncology
- Inflammation
- Immunology

Areas of activities



- R&D: 30% turnover
- 25 Phase III trials in progress

R&D



- Robert J. Hugin

Chief Executive Officer







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# Celgene Corporation

- ✓ 1986: Celanese → Celgene
- ✓ Biotech
- ✓ Specializing in innovation
- ✓ Thalidomide and deracemisation



COURTESY: CELGENE

Headquarters : New Jersey



# 2-2 Celgene around the world

- Biopharmaceutical laboratory specializing in innovation
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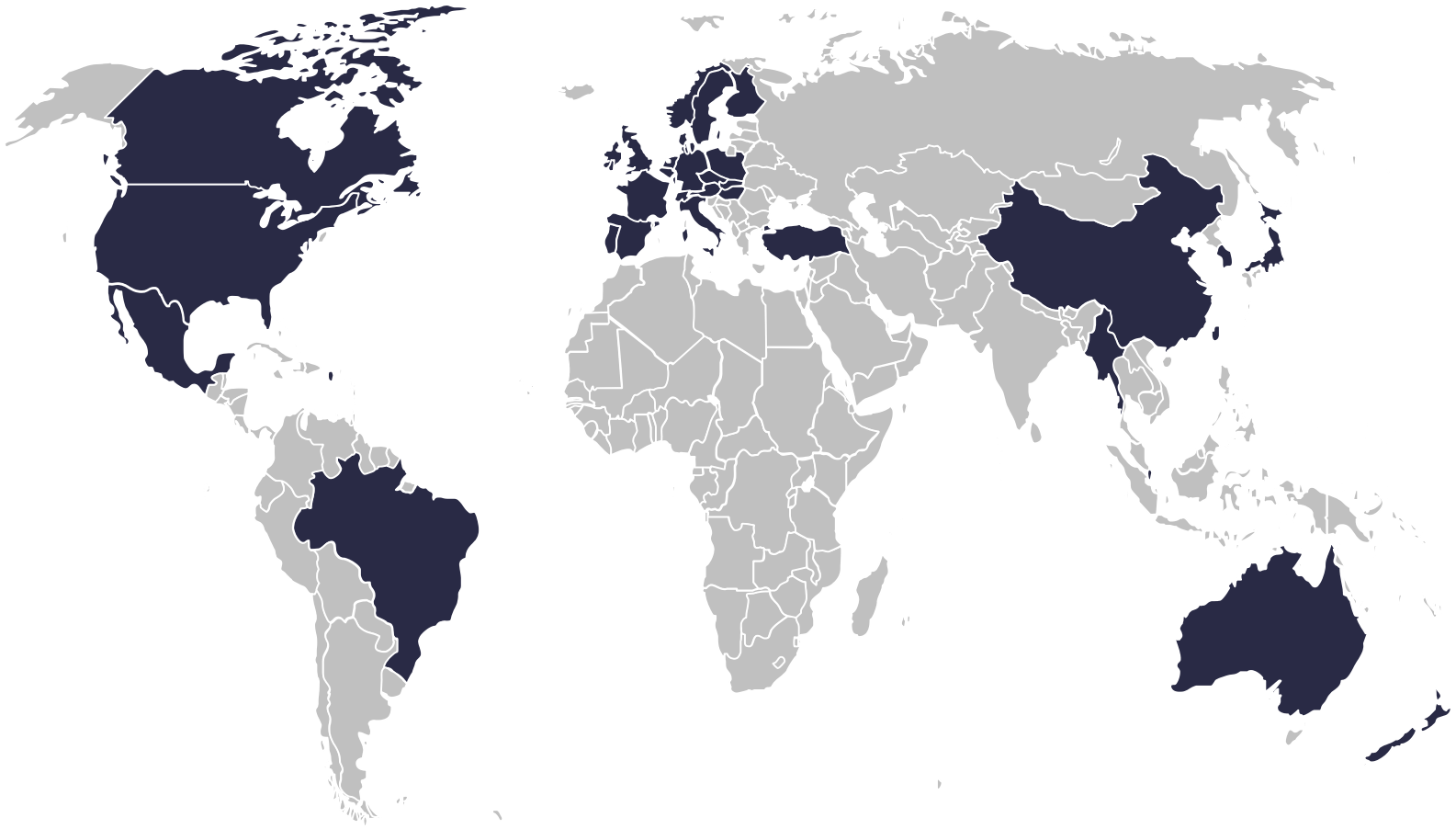
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# Celgene around the world





# 2-3 Areas of activities

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R&D



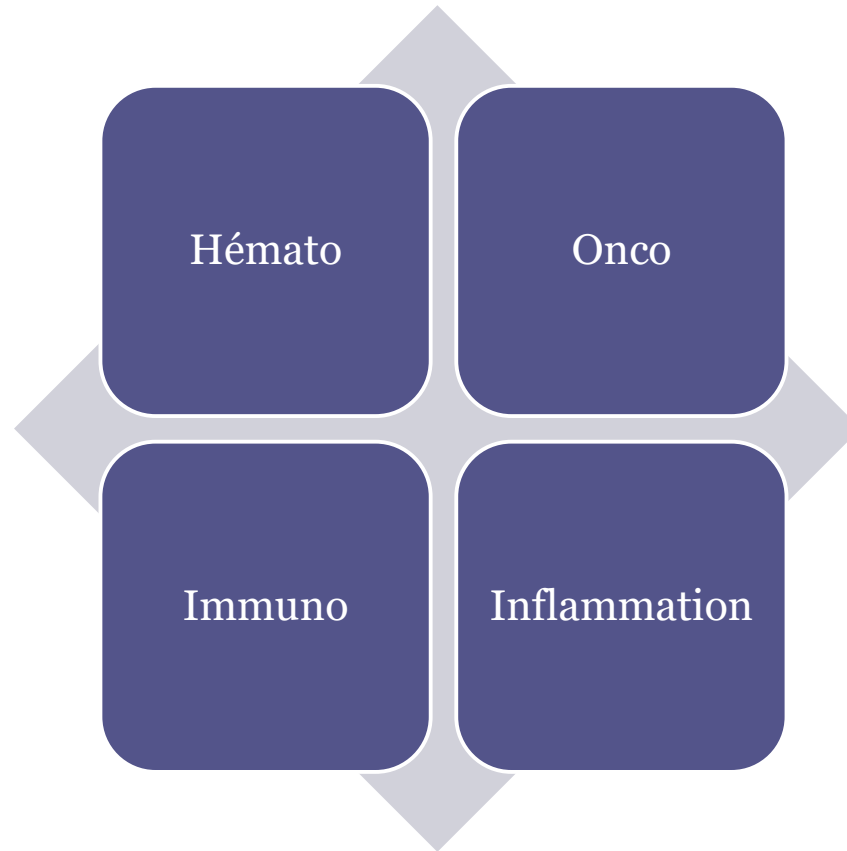
- Robert J.Hugin

Chief Executive Officer



# Areas of activities

Very selective in the choice and development of its molecules  
In search of a real added medical value



Company that integrates all processes by which passes a pharmaceutical product:  
discovery / development / production / clinical-trials / marketing and sales



# 2-4 R&D - Revenue

- Biopharmaceutical laboratory specializing in innovation
- Since 1986

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Headquarters



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In the World



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Areas of activities



- **R&D: 30% turnover**
- **25 Phase III trials in progress**

R&D



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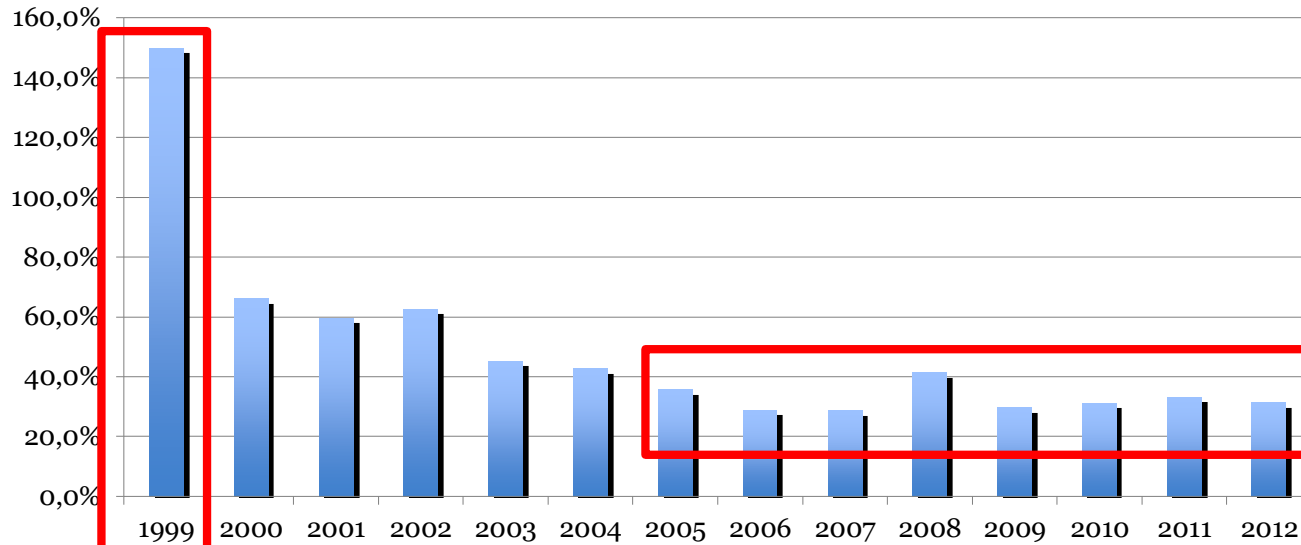
Chief Executive Officer



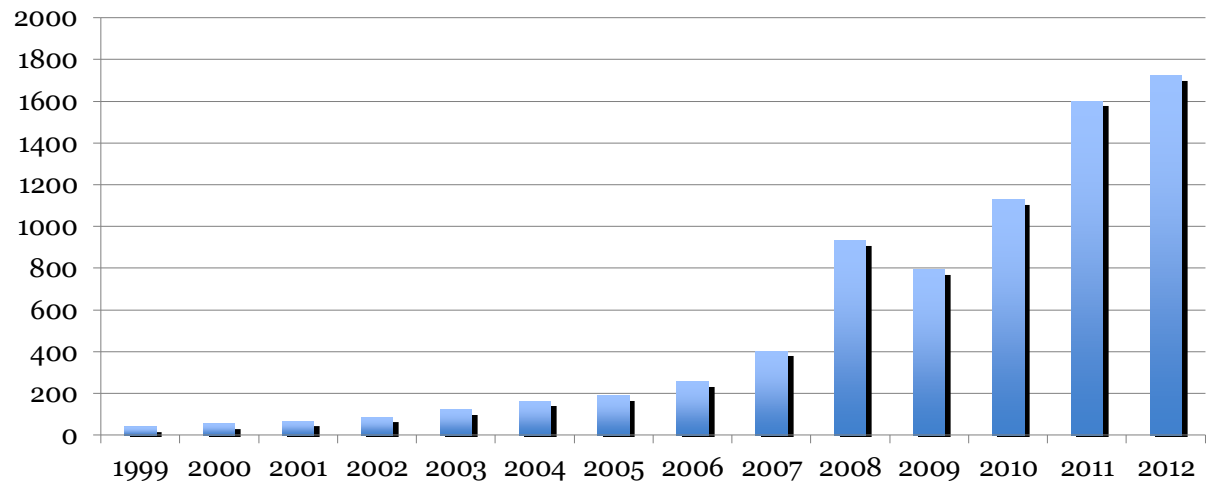




## % of revenue invested in R&D



## "Revenue Invested in R&D (Million dollars)"





# 2-5 CEO and Employees

- Biopharmaceutical laboratory specializing in innovation
- Since 1986

Celgene Corporation



- New Jersey

Headquarters



- Set up in 50 countries
- Patients in 70 countries

In the World



- Hematology
- Oncology
- Inflammation
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Areas of activities



- R&D: 30% turnover
- 25 Phase III trials in progress

R&D



- Robert J.Hugin

Chief Executive Officer





# Bob Hugin - Celgene



**Name:** Bob Hugin

**Title:** Chairman and CEO

**2012 pay:** \$10.57 million

**2011 pay:** \$8.92 million

*We always are looking at the landscape for partnership opportunities and products that have a good value proposition.*

Former Marine officer

Manager at J.P. Morgan & Co.

Joined Celgene as CFO in 1999

Took over as CEO in June 2010

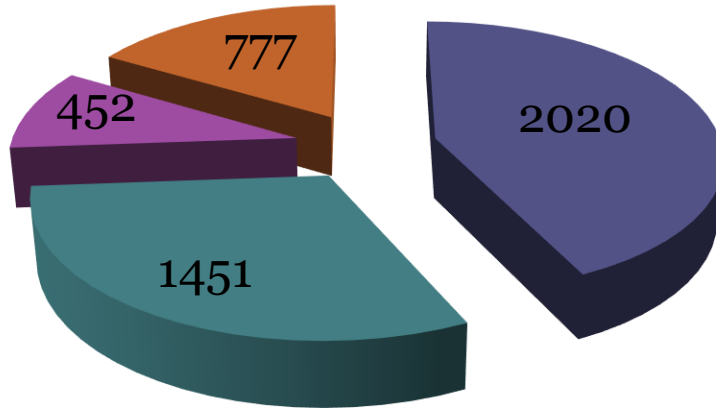
A handwritten signature in blue ink that reads "Robert J. Hugin".

Robert J. Hugin

*Chairman and Chief Executive Officer*

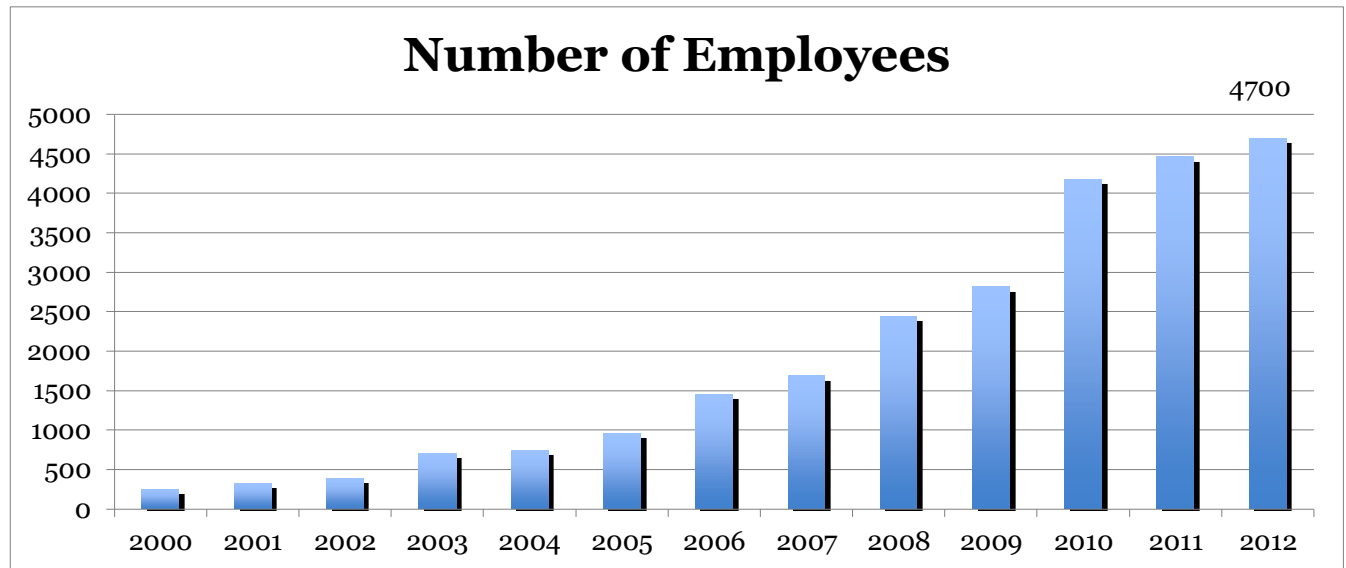


## Employees (2012)



- R and D
- Marketing and sales
- Manufacturing
- Direction and Administration

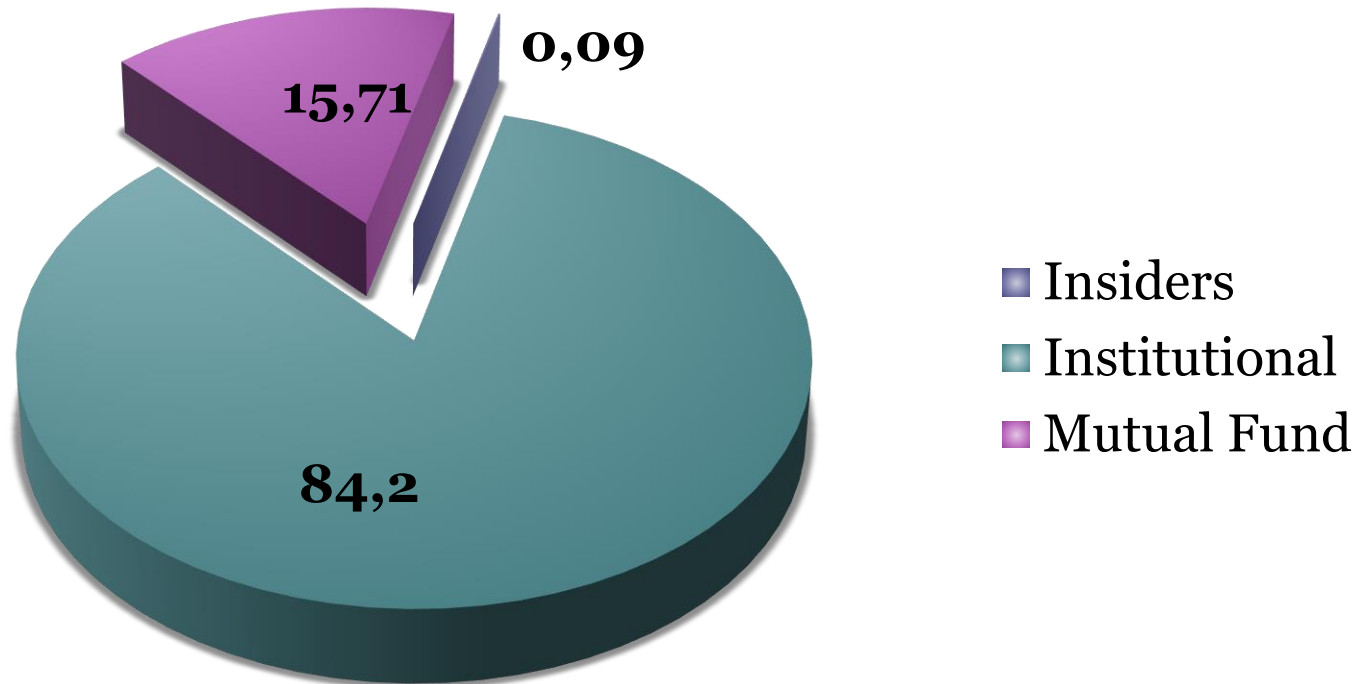
## Number of Employees





# Share Holders Distribution

Share Holders  
(Jan. 2014 - source Macroaxis.com)



# At the beginning of Celgene (1986)

*OCDE: Association between Life Sciences and a set of modern techniques*

- ✓  *Innovation*
- ✓  *Revenue invested in R&D*
- ✓  *Origin and spirit of a small pharma*
- ✓  *Losing money*

→ **Biotech**

# 3 – CELGENE'S STRATEGY







# Celgene's vision and missions

Global biopharmaceutical company

Discovery, development, commercialization

Innovative therapies for unmet medical needs

Cancer & Immune-inflammatory diseases



# Registered products

**Vidaza**<sup>®</sup>  
azacitidine for injection

Please see full Prescribing Information, including CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS.

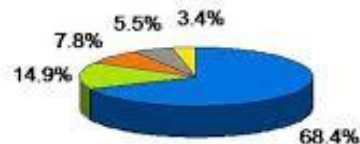
**THALOMID**<sup>®</sup>  
(thalidomide) Capsules

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS.

**Pomalyst**<sup>®</sup>  
(pomalidomide) capsules

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS.

Celgene 2012 Revenue Breakdown



■ Revlimid ■ Vidaza ■ Abraxane ■ Thalomid ■ Other

**ISTODAX**<sup>®</sup>  
(romidepsin) for injection

Please see full Prescribing Information, including WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS.

**Abraxane**<sup>®</sup>  
for Injectable Suspension  
(paclitaxel protein-bound particles for injectable suspension)  
(albumin-bound)

Please see full Prescribing Information, including Boxed WARNING, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS.

**Revlimid**<sup>®</sup>  
(lenalidomide) capsules  
2.5 · 5 · 10 · 15 · 20 · 25 mg



# Celgene's strategy



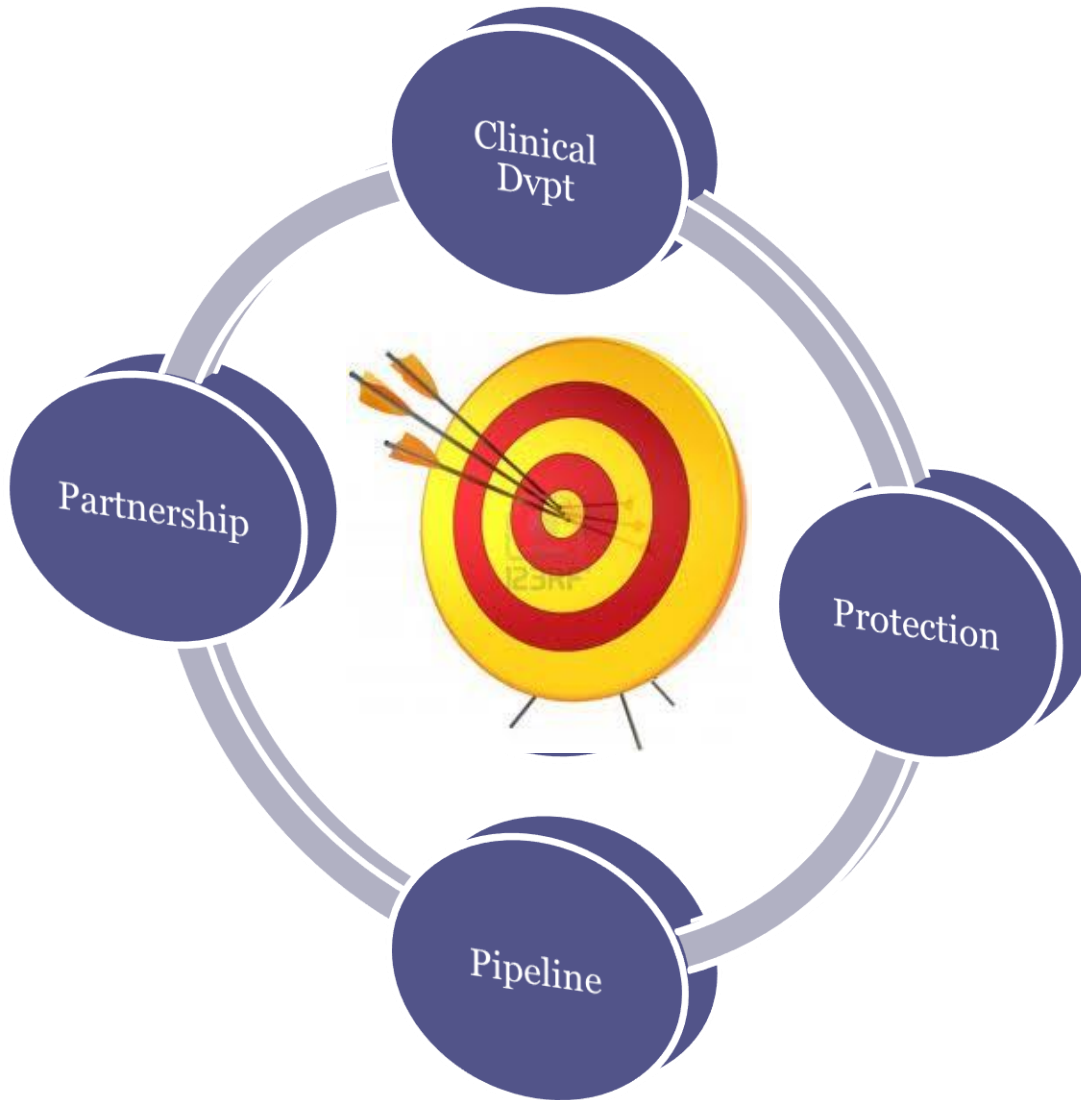
*Financial results for 2012 were outstanding.  
These results underscore the strength and leverage  
of our business model*

I have never been more optimistic about where our company is heading. **Celgene is on the move.**

A handwritten signature in blue ink that reads "Robert J. Hugin".

Robert J. Hugin

*Chairman and Chief Executive Officer*





# Clinical development – Key points

A teal-colored downward-pointing arrow shape, serving as a background for the "Expertise" label.

## Expertise

- Capitalizing on Hematology
- Building new franchises in Oncology and I&I

A dark blue-colored downward-pointing arrow shape, serving as a background for the "Maximising" label.

## Maximising

- New indications of existing product
- Treatment of a disease at ALL stages

A purple-colored downward-pointing arrow shape, serving as a background for the "Innovation" label.

## Innovation

- Pipeline of new drug candidates
- Strategic collaboration

# Clinical development – Key points

## Expertise

- Capitalizing on Hematology
- Building new franchises in Oncology and I&I

## Maximising

- New indications of existing product
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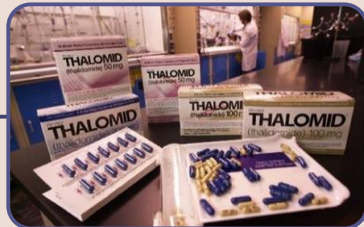
## Innovation

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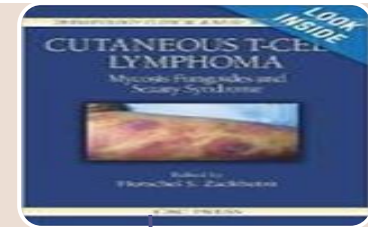
# Hematology Franchise

**Fighting Multiple Myeloma**  
Breakthroughs in Treatment Of This Deadly Blood Cancer

GO



**Myelodysplastic syndromes**  
Achievements in understanding and treatment





# Established player in the blood cancer market





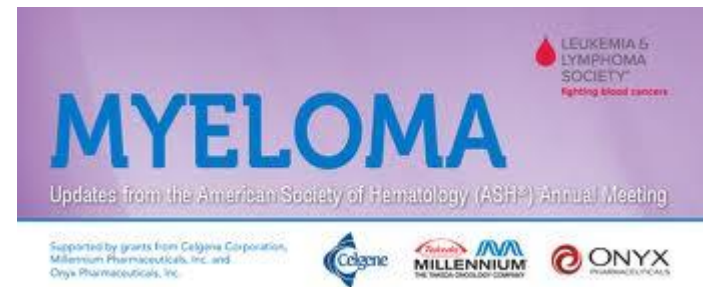
# Established player in the blood cancer market





# Expertise

- 160 abstracts submitted to ASH 2013 on Celgene therapies
- **100 abstracts on Revlimid® alone**



# Clinical development – Key points

## Expertise

- Capitalizing on Hematology
- Building new franchises in Oncology and I&I

## Maximising

- **New indications of existing product**
- Treatment of a disease at ALL stages

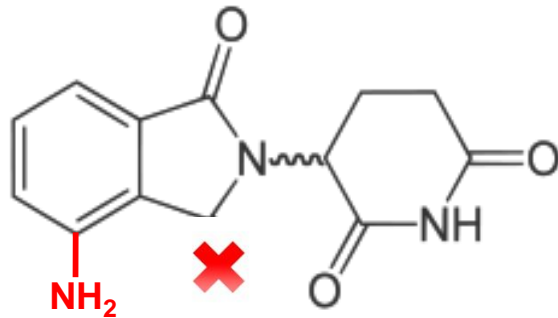
## Innovation

- Pipeline of new drug candidates
- Strategic collaboration



# Hematology Franchise

## IMiDs in Multiple Myeloma



Thalidomide **THALOMID®**

Lenalidomide **REVLIMID®**

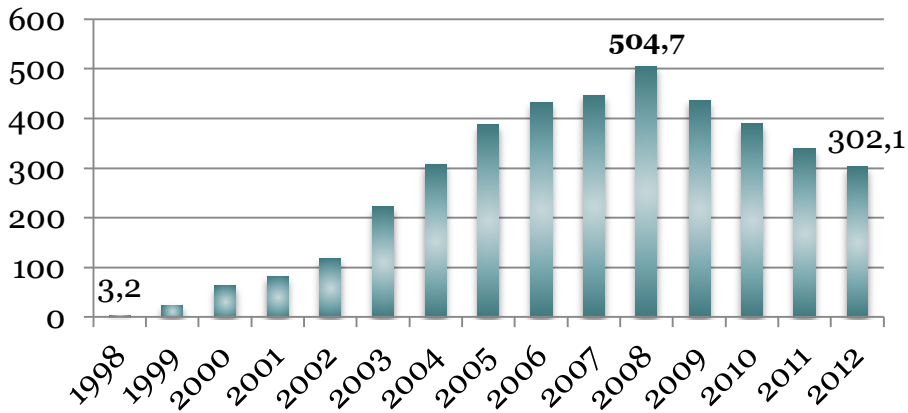
Pomalidomide **POMALYST®/IMNOVID®**



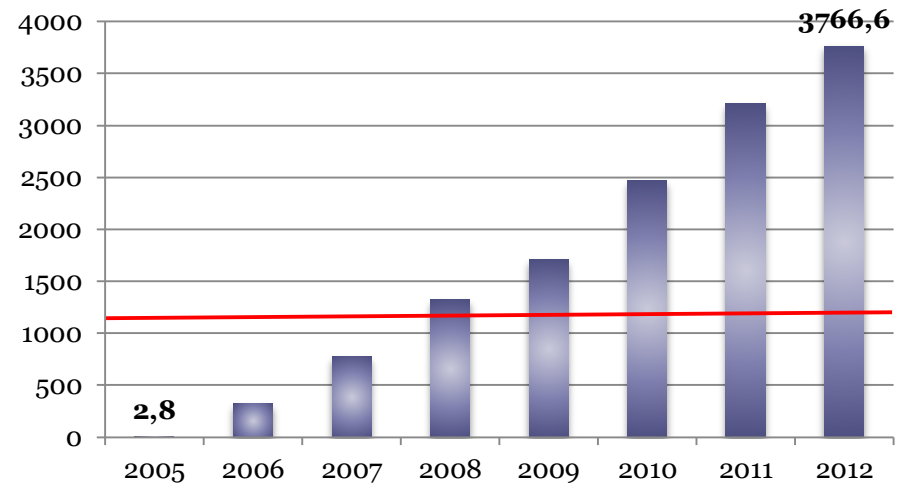


# Revenues – Thalidomide<sup>®</sup> / Revlimid<sup>®</sup>

(Million \$)



(Million \$)



# Clinical development – Key points

## Expertise

- Capitalizing on Hematology
- Building new franchises in Oncology and I&I

## Maximising

- New indications of existing product
- **Treatment of a disease at ALL stages**

## Innovation

- Pipeline of new drug candidates
- Strategic collaboration



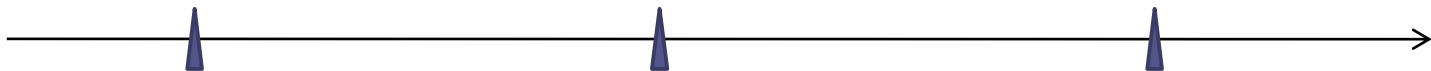
# Treatment of MM at ALL stages



May 2006 (US)  
April 2008 (EU)

June 2006 (US)  
June 2007 (EU)

Feb 2013 (US)  
August 2013 (EU)



Thalomid®

Revlimid®

Pomalyst/  
Immovid®

**First line**

**After at least one  
prior therapy**

**Resistant and  
refractory MM (at least  
two prior therapies)**

**First line**

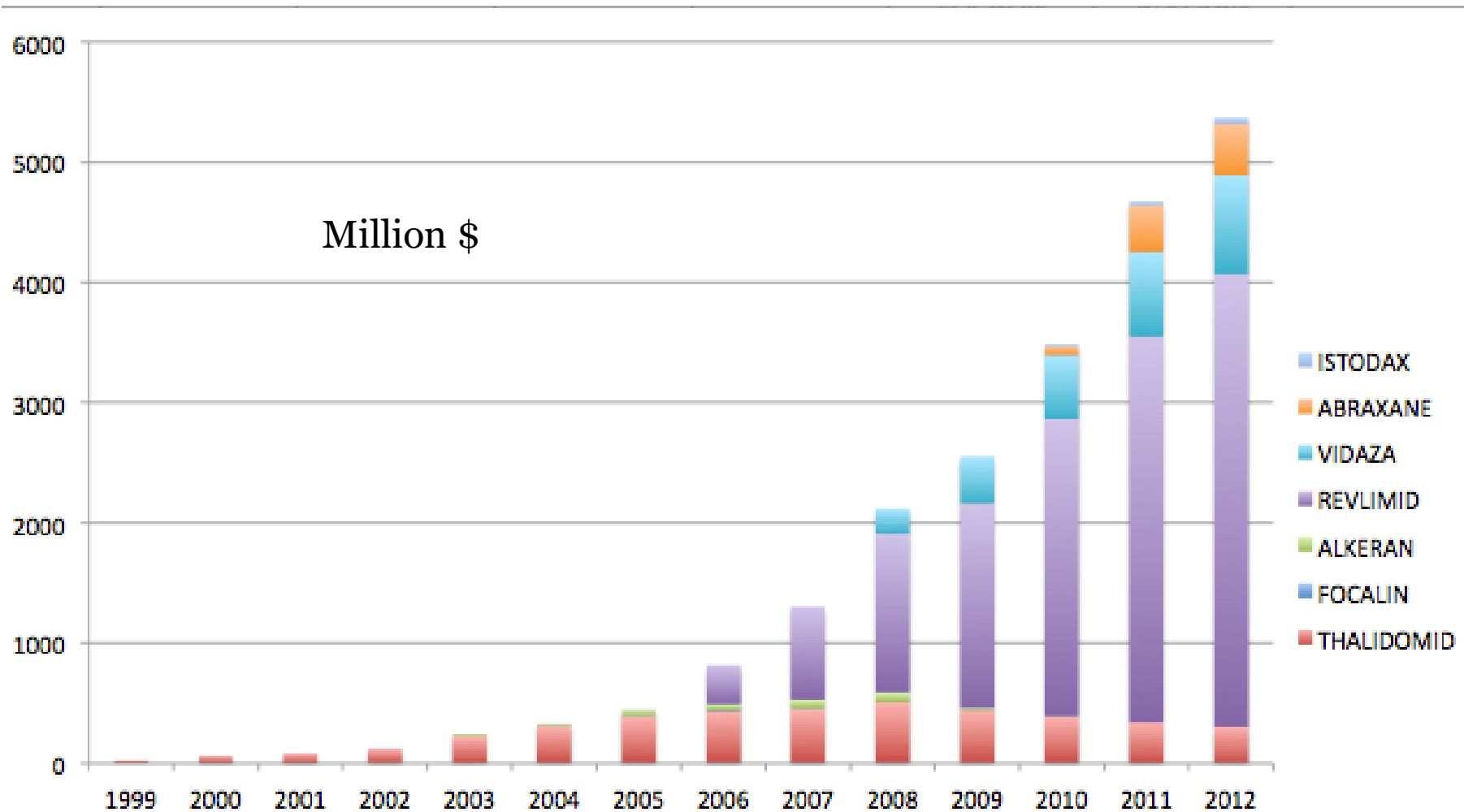
**Off label use**

**Second line**





# Celgene's revenues



# Clinical development – Key points

## Expertise

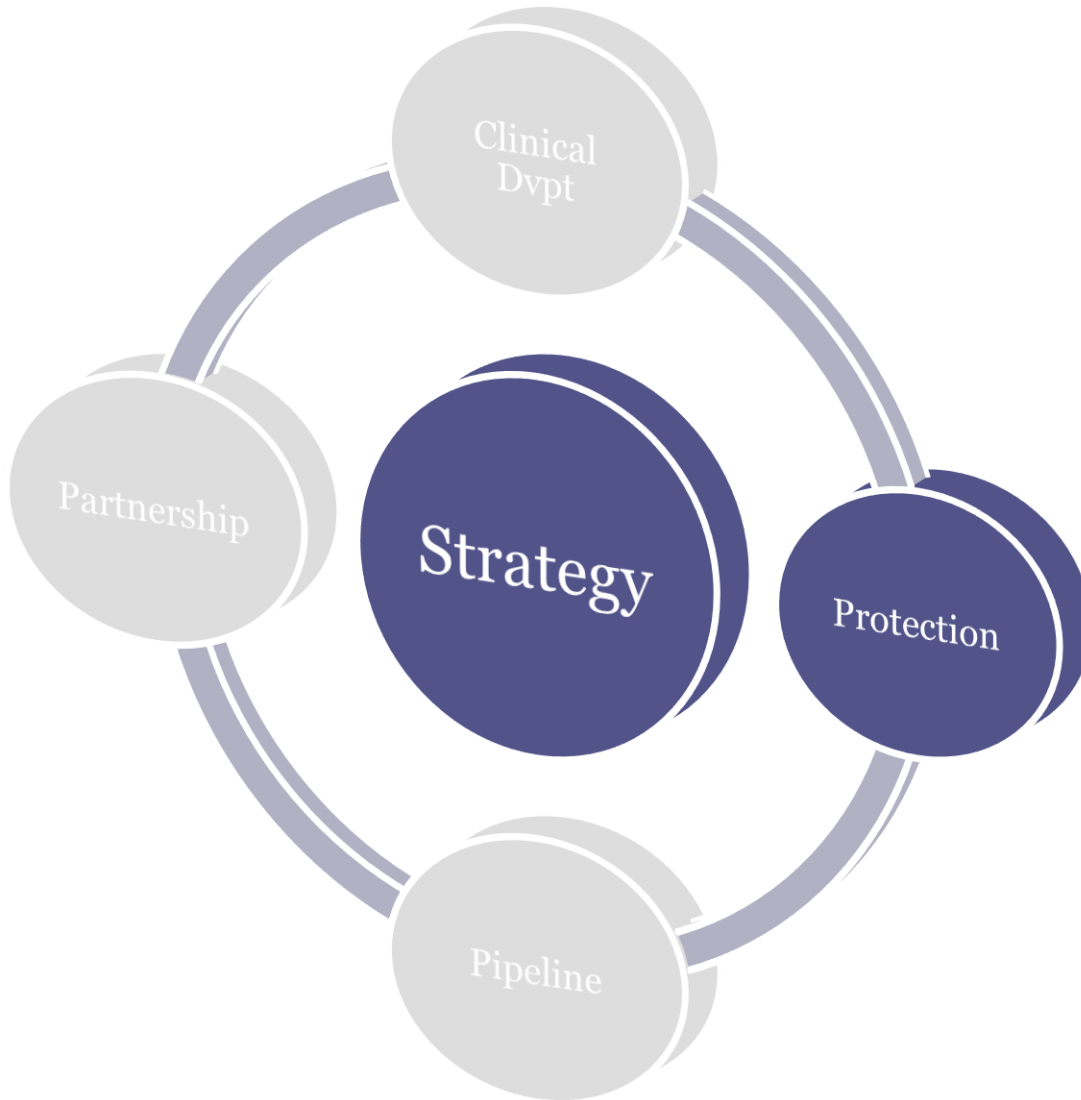
- Capitalizing on Hematology
- Building new franchises in Oncology and I&I

## Maximising

- New indications of existing product
- Treatment of a disease at ALL stages

## Innovation

- Pipeline of new drug candidates
- Strategic collaboration





# PROTECTION

*« We consider intellectual property protection to be critical to our operations »*



- Total of
  - 400 patents (US)
  - 500 pending patent applications (US)
  - + foreign patent rights corresponding to most of the US patents
  - Regulatory exclusivities
  - Brand names, logos

**THALOMID REMS™**



# PROTECTION

## No big patent cliffs approaching

	U.S.	Europe
<b>REVLIMID® brand drug</b> (U.S. and European Patent Office, or EPO, drug substance patents)	2027	2024
<b>THALOMID® brand drug</b> (Use and/or drug product patents)	2023	2019
<b>VIDAZA® brand drug</b> (U.S. and EMA regulatory exclusivities only)	2011	2018
<b>ABRAXANE® brand drug</b> (U.S. use and EPO use/drug product patents)	2026	2022
<b>ISTODAX® brand drug</b> (U.S. drug substance patents) (EMA regulatory exclusivity upon approval)	2021	(10 years regulatory exclusivity upon approval)
<b>POMALYST® brand drug</b> (U.S. use patent) (EMA regulatory exclusivity upon approval)	2024	(10 years regulatory exclusivity upon approval)

# PROTECTION of Revlimid

- **Patent** protected until 2024 (EU)  
until 2027 (US)
  - last-to-expire patent 2027 (US) polymorphic forms of active ingredient
  - 2024 (EU) + **SPC** in Spain, France, Italy, Germany and the UK.
  - **Orphan drug** status
  - **PIP** : Treatment of diffuse large B-cell lymphoma /Myelodysplastic Syndrome



VELCADE® (Takeda) loses patent protection in early 2014





# Pipeline (1/2)

Strong late-stage pipeline

**Data on over 10 phase 3 trials in 2013**  
including data on trials for **Revlimid<sup>®</sup> for newly**  
**diagnosed MM.**





# Phase III trials of commercial stage products

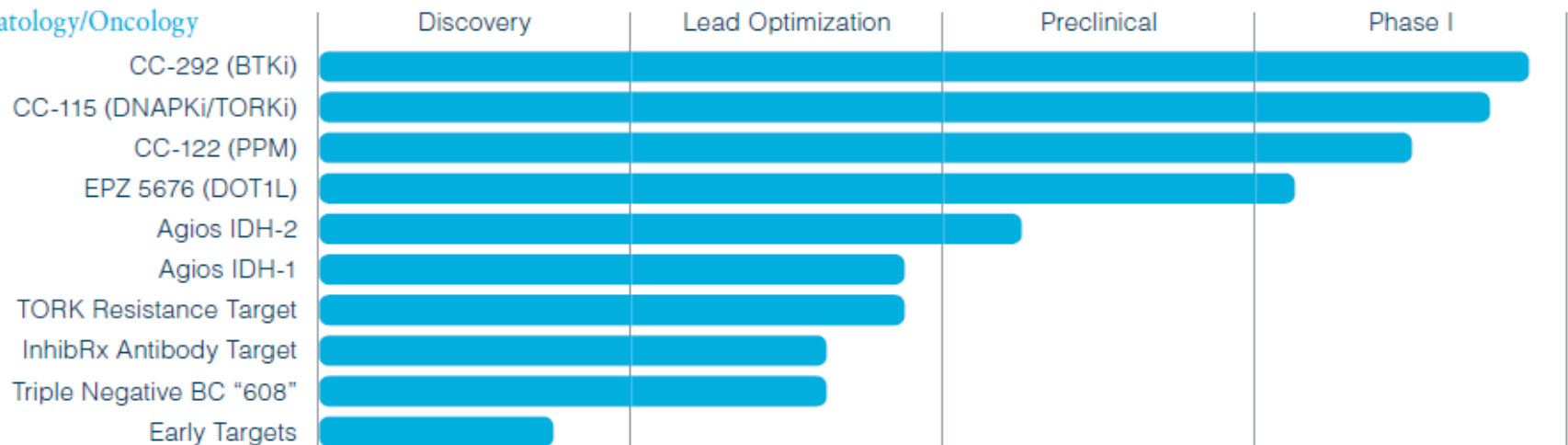
Product	Disease Indication	Status	Trial Beginning Date
REVLIMID®	Newly diagnosed multiple myeloma	Phase III ongoing	August 2008
	Maintenance therapy for multiple myeloma	Phase III trials ongoing	December 2004
	MDS del 5q	Submitted EU regulatory filing	
	MDS non-del 5q	Phase III ongoing	February 2010
	Mantle cell lymphoma for U.S. filing	Phase II completed, Submitted U.S. regulatory filing	
	Mantle cell lymphoma for EU filing	Phase II ongoing	April 2009
	Diffuse large B cell lymphoma	Phase II/III ongoing	July 2010
	Diffuse large B cell lymphoma maintenance	Phase III enrolling	May 2009
	Follicular lymphoma consolidation & maintenance	Phase III enrolling	December 2011
	CLL first-line	Phase III enrolling	November 2009
CLL maintenance	Phase III enrolling	February 2009	
VIDAZA®	AML	Phase III enrolling	October 2010
ABRAXANE®	Pancreatic cancer	Phase III completed, U.S. and EU regulatory filings pending	
	Melanoma	Phase III ongoing	April 2009
POMALYST® (pomalidomide)	Myelofibrosis	Phase III ongoing	September 2010
	Multiple myeloma	Phase II completed, Submitted EU regulatory filings	
	Multiple myeloma	Phase III ongoing Additional phase I, II, III trials enrolling	April 2011
	Systemic Sclerosis	Phase II enrolling	March 2012 June 2012



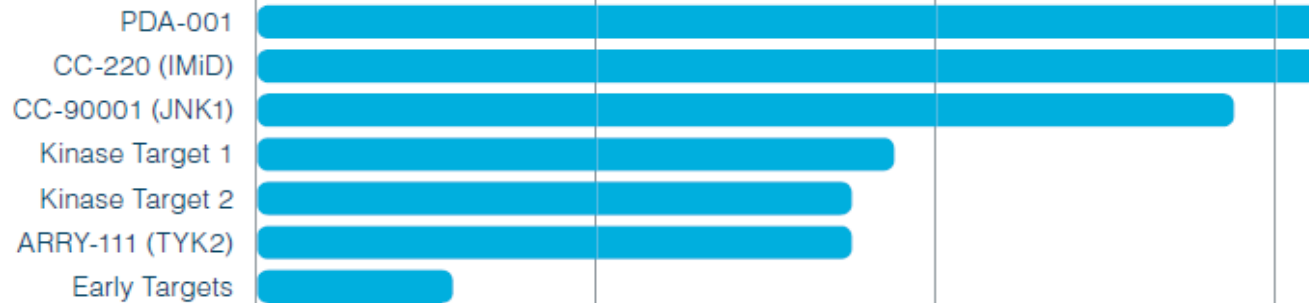
# Pipeline (2/2)

## RESEARCH & EARLY DEVELOPMENT

### Hematology/Oncology



### Inflammation & Immunology





# Partnership

## 1. Acquisitions

- Strengthen research & manufacturing capabilities
- Enhance commercial product portfolio

## 2. Alliances

- With small development companies (promising candidates in pre-clinical /early stages)
- Shape future pipeline

# Partnership

## 1. Acquisitions

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## 1.Acquisitions

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## 1.Acquisitions

- Strengthen research & manufacturing capabilities
- Enhance commercial product portfolio



## Signal Pharmaceuticals ( 2000)

- Biopharmaceutical company
- Focused on the discovery & development of drugs that **regulate genes associated with disease**

The logo for Anthrogenesis consists of the word "ANTHROGENESIS" in a bold, black, sans-serif font, centered within a white rounded square frame.

ANTHROGENESIS

## Anthrogenesis (2002)

- Biotherapeutics company
- Engaged in the research, recovery culture-expansion, preservation, development & distribution of **placental stem cells as therapeutic agents.**



## Avila Therapeutics (2012)

- Biotechnology company
- Platform for developing targeted covalent drugs that treat diseases through **protein silencing**



## 1.Acquisitions

- Strengthen research & manufacturing capabilities
- Enhance commercial product portfolio



Pharmion (2008)

→ **VIDAZA<sup>®</sup>**

- Biopharmaceutical company
- **2,9 billions \$**



Gloucester Pharmaceuticals (2010)

→ **ISTODAX<sup>®</sup>**

- Biopharmaceutical company
- **340 millions \$**



Abraxis BioScience (2010)

→ **ABRAXANE<sup>®</sup>**

- Biotechnology company
- **2.9 Billions \$**



Pharmion (2008)

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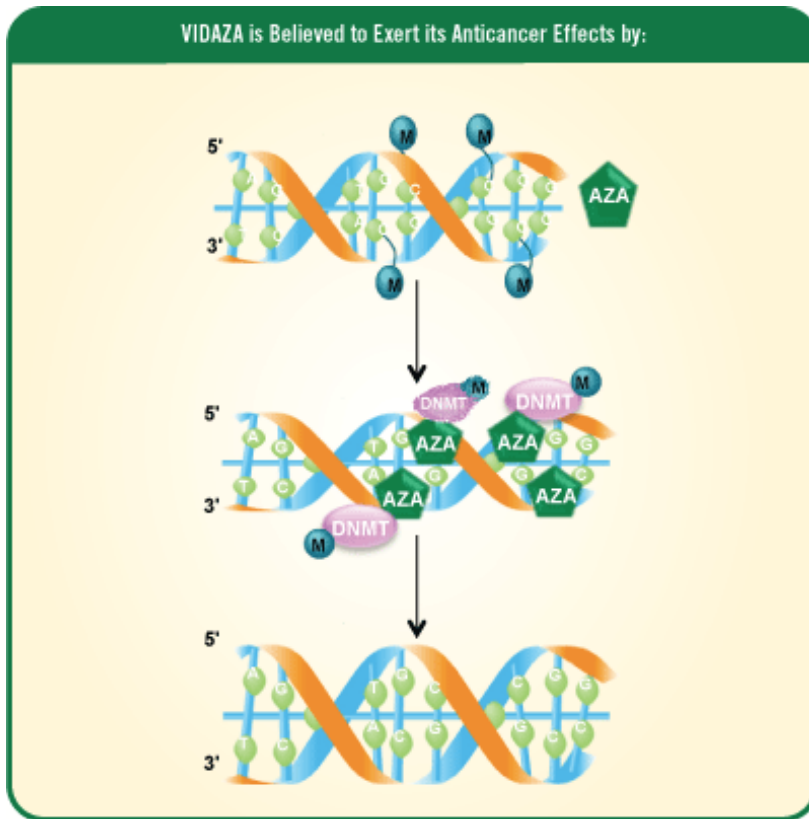
- Biotechnology company
- **2.9 Billions \$**

# Vidaza<sup>®</sup> Azacitidine

- is a pyrimidine nucleoside analog of cytidine
- Vidaza<sup>®</sup> is approved in the US and Europe for myelodysplastic syndromes (2008)
- Mechanism of actions:

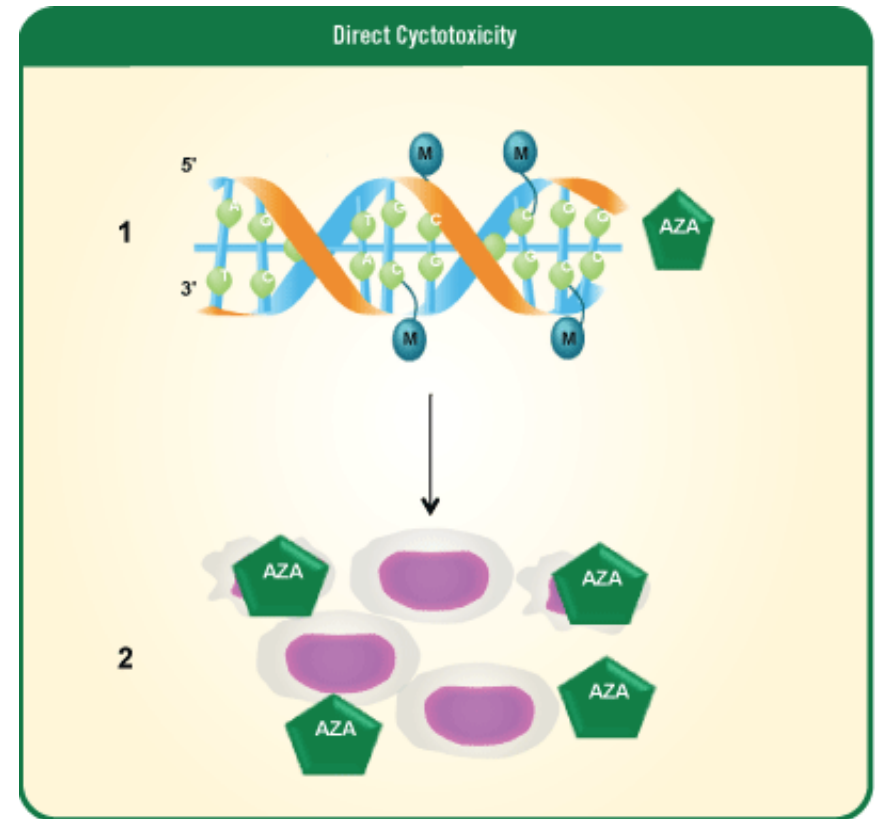


VIDAZA® is believed to have the following two Mechanisms of Actions:



↓

**Hypomethylation of DNA**



↓

**Direct cytotoxicity**



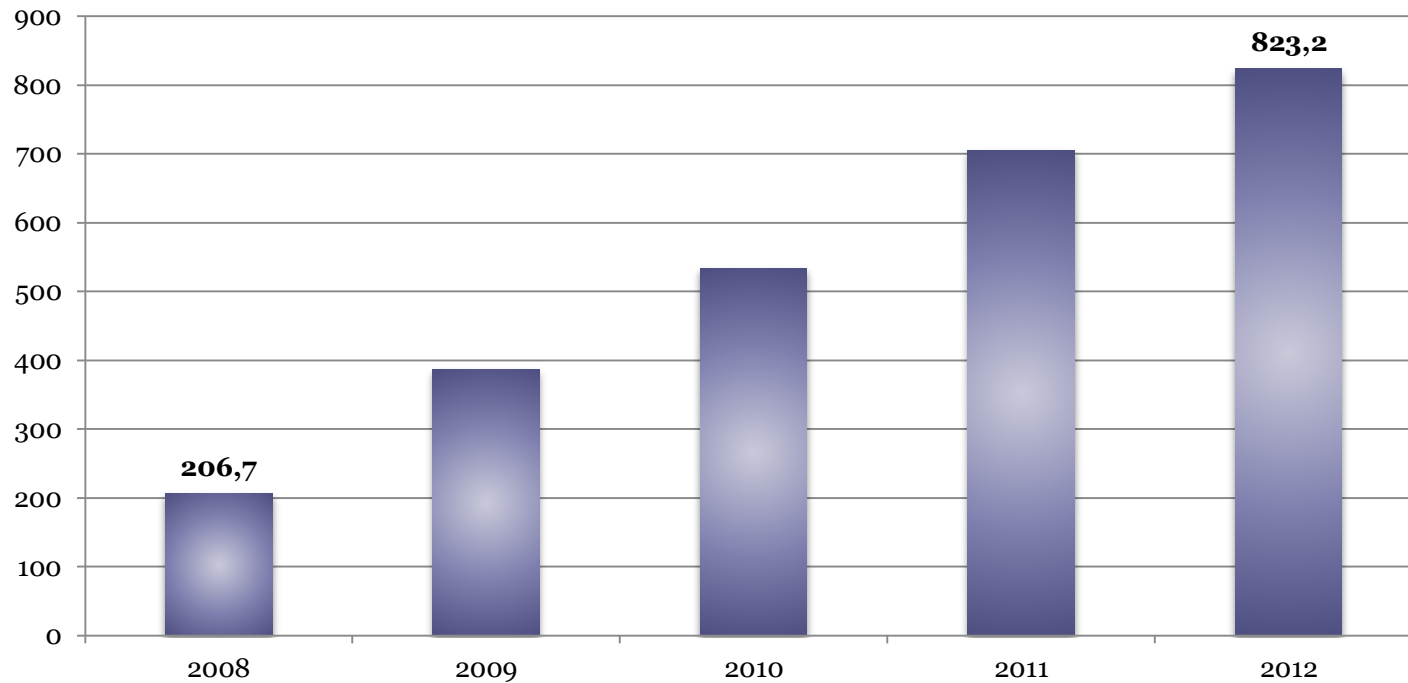
# VIDAZA<sup>®</sup> (azacitidine)

- generic in the US (may 2011 – market 2013)
- full potential:
  - in **Europe** (orphan drug exclusivity through the end of **2018**)
  - others international markets (until January **2021** in **Japan**)
- Results from Phase 3 study in elderly newly diagnosed expected by 2014



# VIDAZA<sup>®</sup> (azacitidine)

**Vidaza (Revenues)**  
(Million \$)





Pharmion (2008)

→ VIDAZA®

- Biopharmaceutical company
- 2,9 billions \$



Gloucester Pharmaceuticals (2010)

→ ISTODAX®

- Biopharmaceutical company
- 340 millions \$



Abraxis BioScience (2010)

→ ABRAXANE®

- Biotechnology company
- 2.9 Billions \$



# Istodax<sup>®</sup> Romidepsin

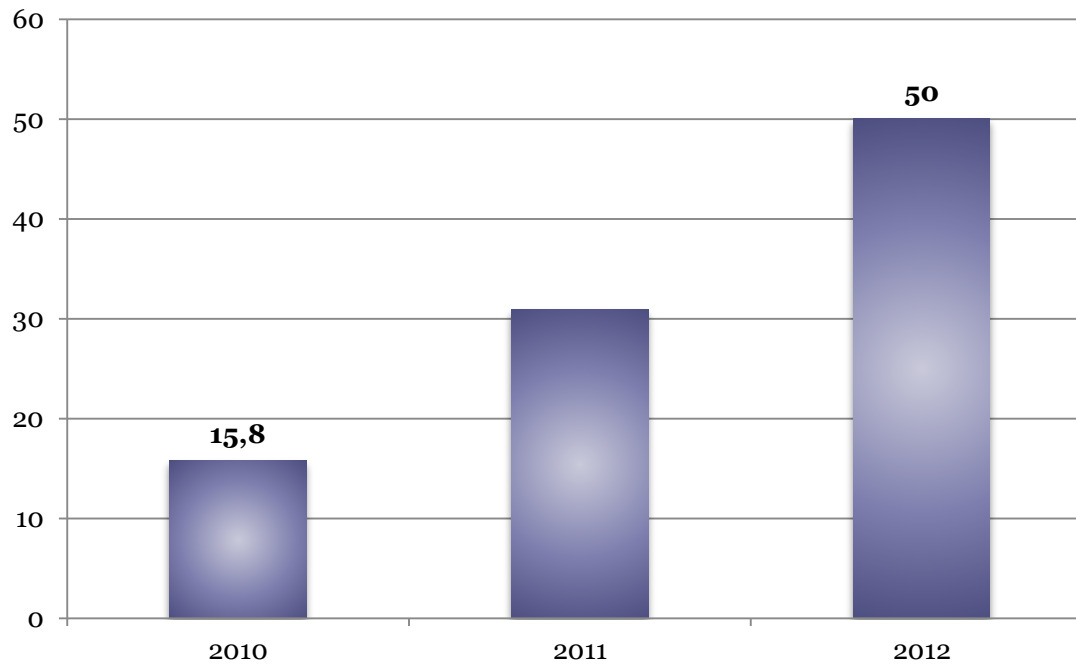
- The **first and only drug** approved in both peripheral and cutaneous T-cell lymphoma (**PTCL-CTCL**) in US
- a histone deacetylase (HDAC) inhibitor
- obtained from the bacteria *Chromobacterium violaceum*





# Istodax<sup>®</sup> Romidepsin

**Istodax (Revenues)**  
(Million \$)





Pharmion (2008)

→ VIDAZA®

- Biopharmaceutical company
- 2,9 billions \$



Gloucester Pharmaceuticals (2010)

→ ISTODAX®

- Biopharmaceutical company
- 340 millions \$



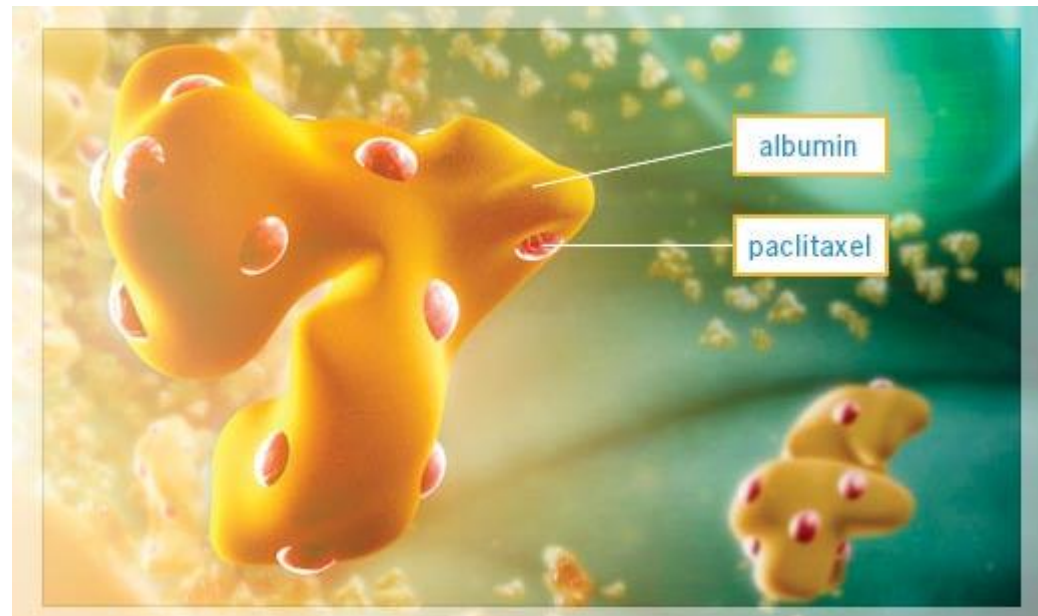
Abraxis BioScience (2010)

→ ABRAXANE®

- Biotechnology company
- 2.9 Billions \$

# ABRAXANE<sup>®</sup> (Nab-paclitaxel)

- Cornerstone therapy for the treatment of multiple **solid tumor cancers**
- Injectable suspension



## Abraxane's expanded therapeutic indications:

### Non Small Cell Lung Cancer

Oct 2012 (US)

→ First line

2

1

### Metastatic Breast Cancer

Jan 2005 (US)

Jan 2008 (EU)

→ 2<sup>nd</sup> line

3

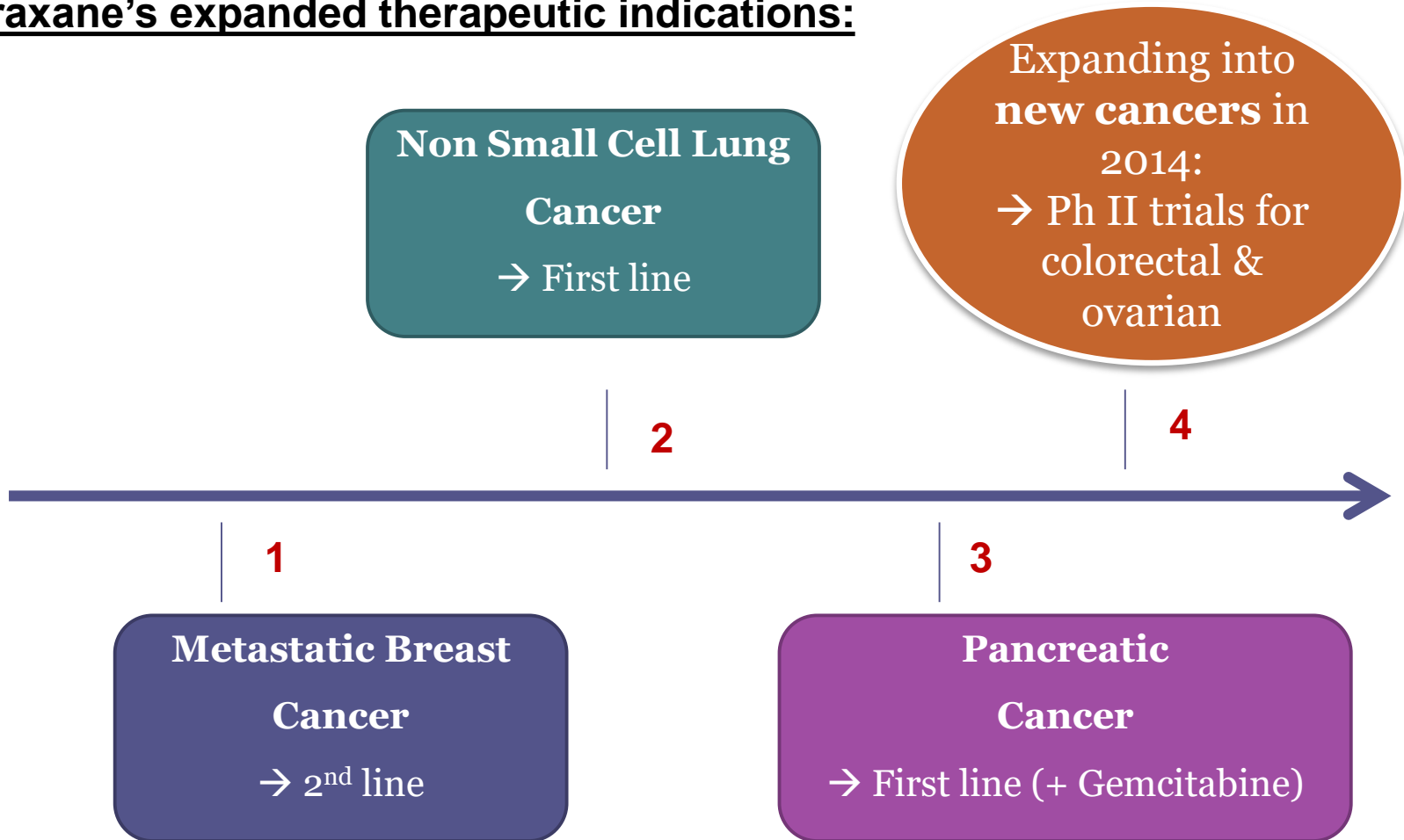
### Pancreatic Cancer

Sept 2013 (US)

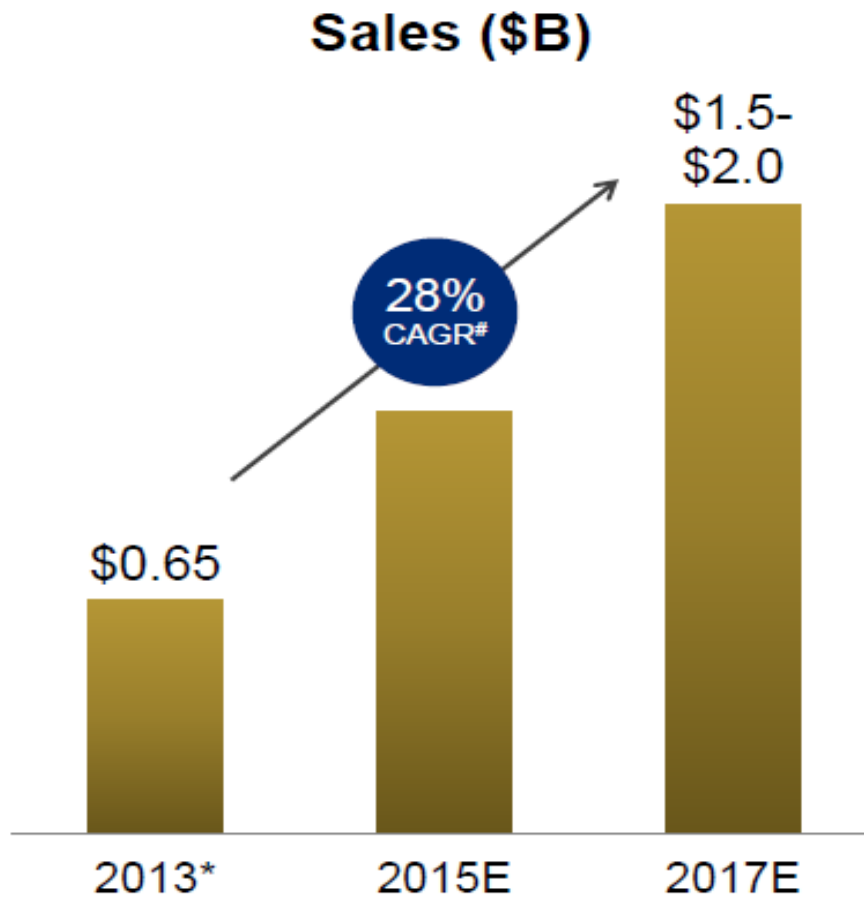
Nov 2013 (EU)

→ First line (+ Gemcitabine)

## Abraxane's expanded therapeutic indications:



# ABRAXANE<sup>®</sup> (Nab-paclitaxel)



**BLOCKBUSTER !!!**

## 1. Acquisitions

- Strengthen research & manufacturing capabilities
- Enhance commercial product portfolio

## 2. Alliances

- With small development companies (promising candidates in pre-clinical /early stages)
- Shape future pipeline

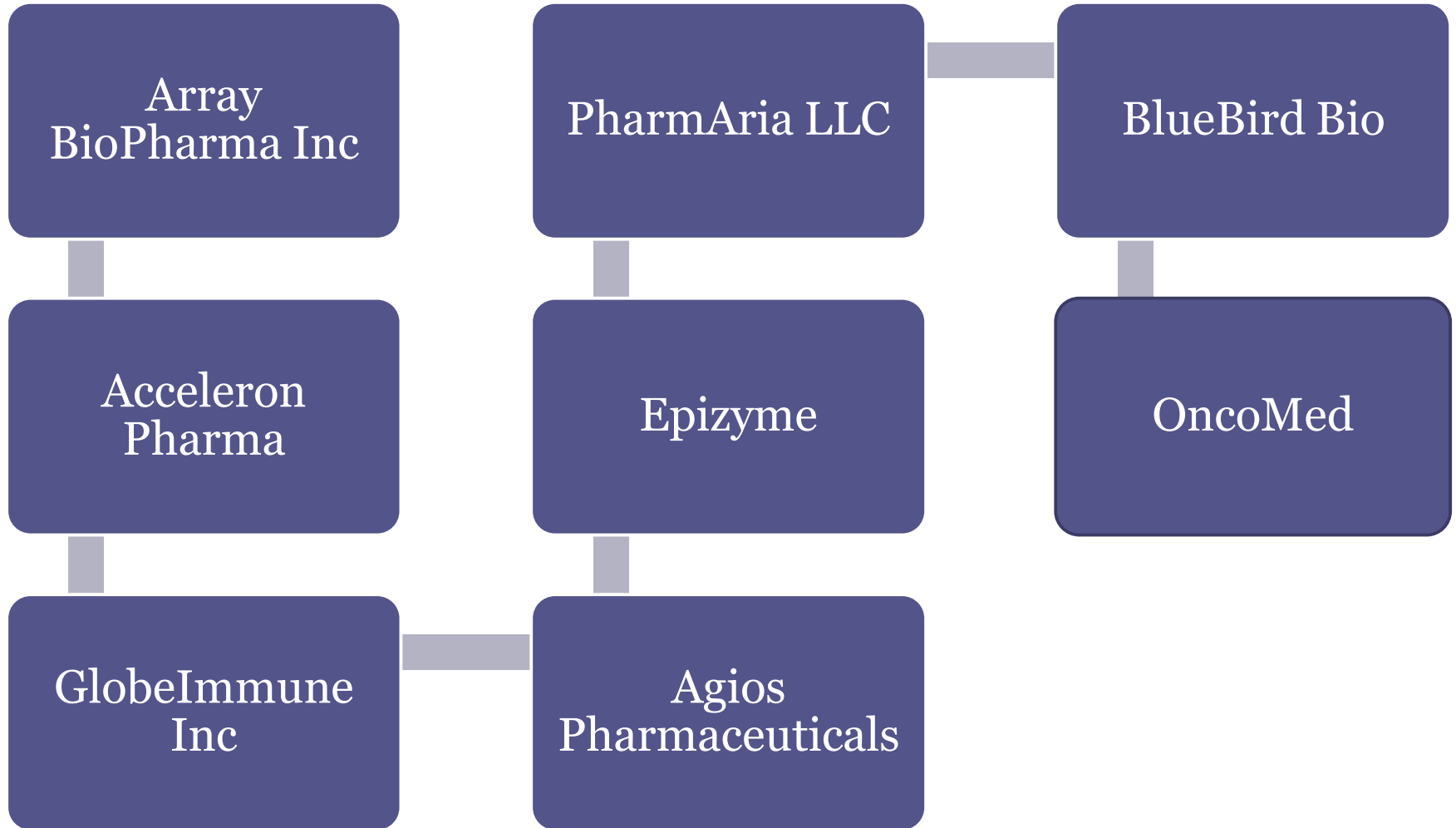


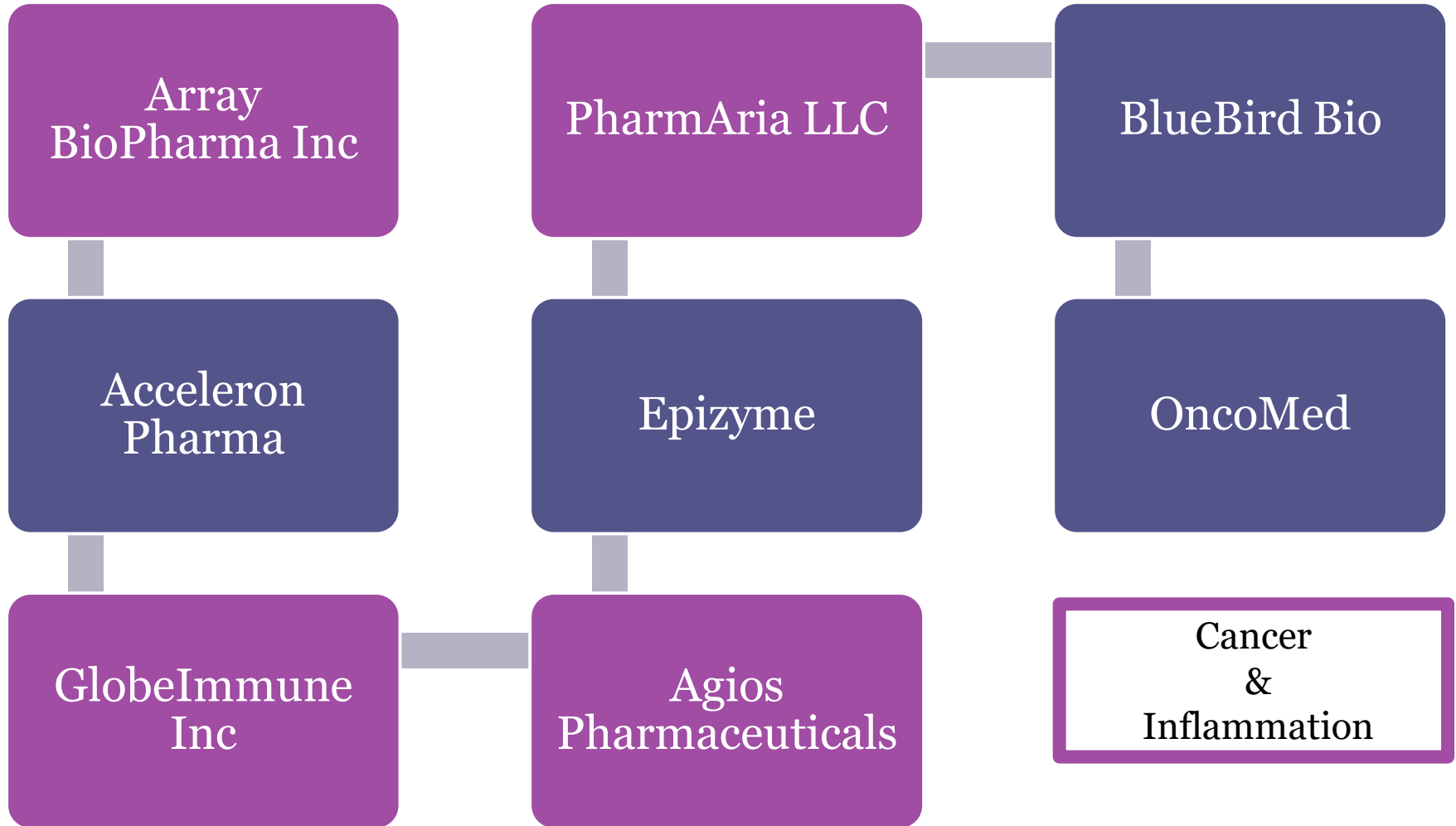
## 1. Acquisitions

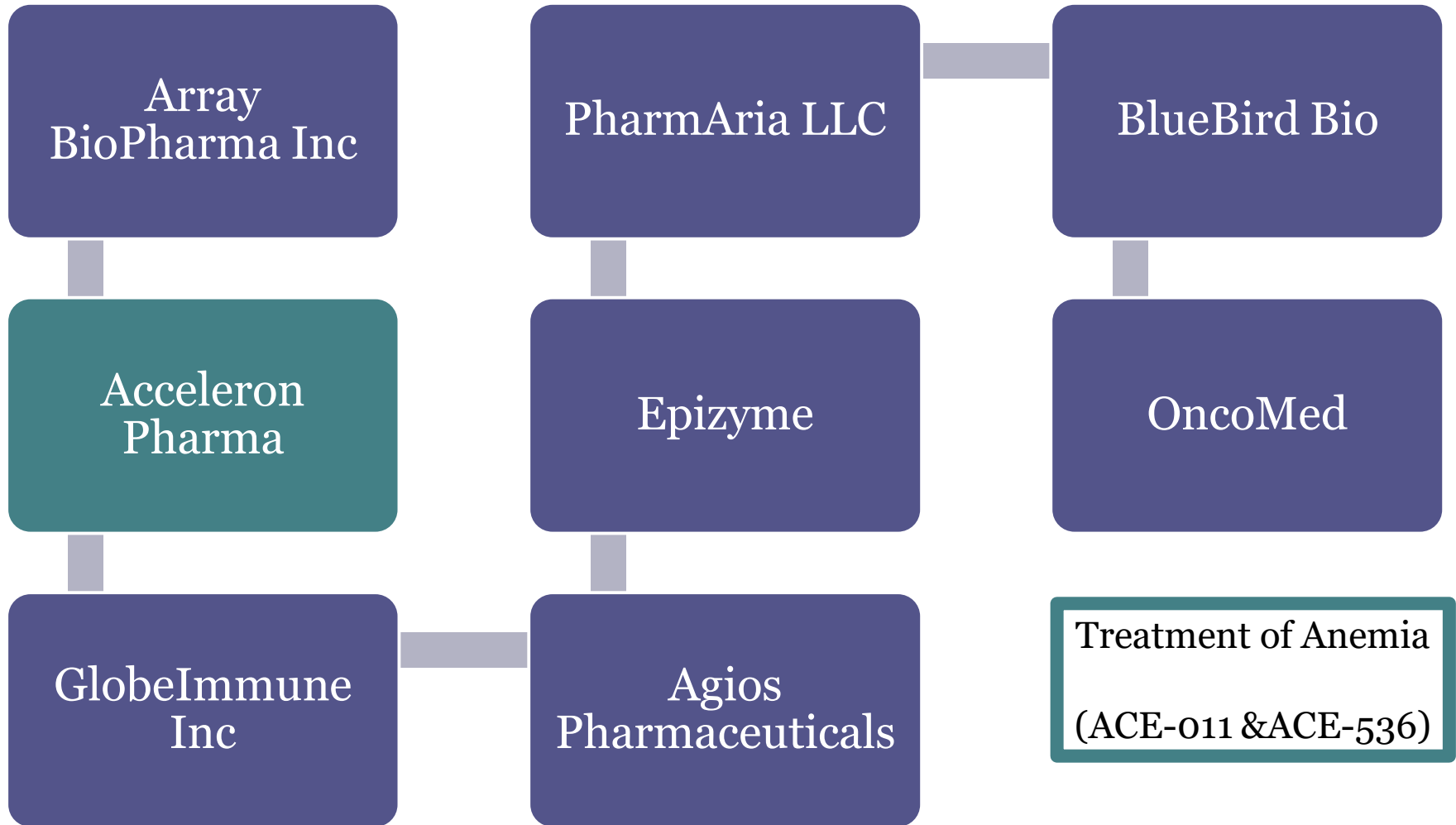
- Strengthen research & manufacturing capabilities
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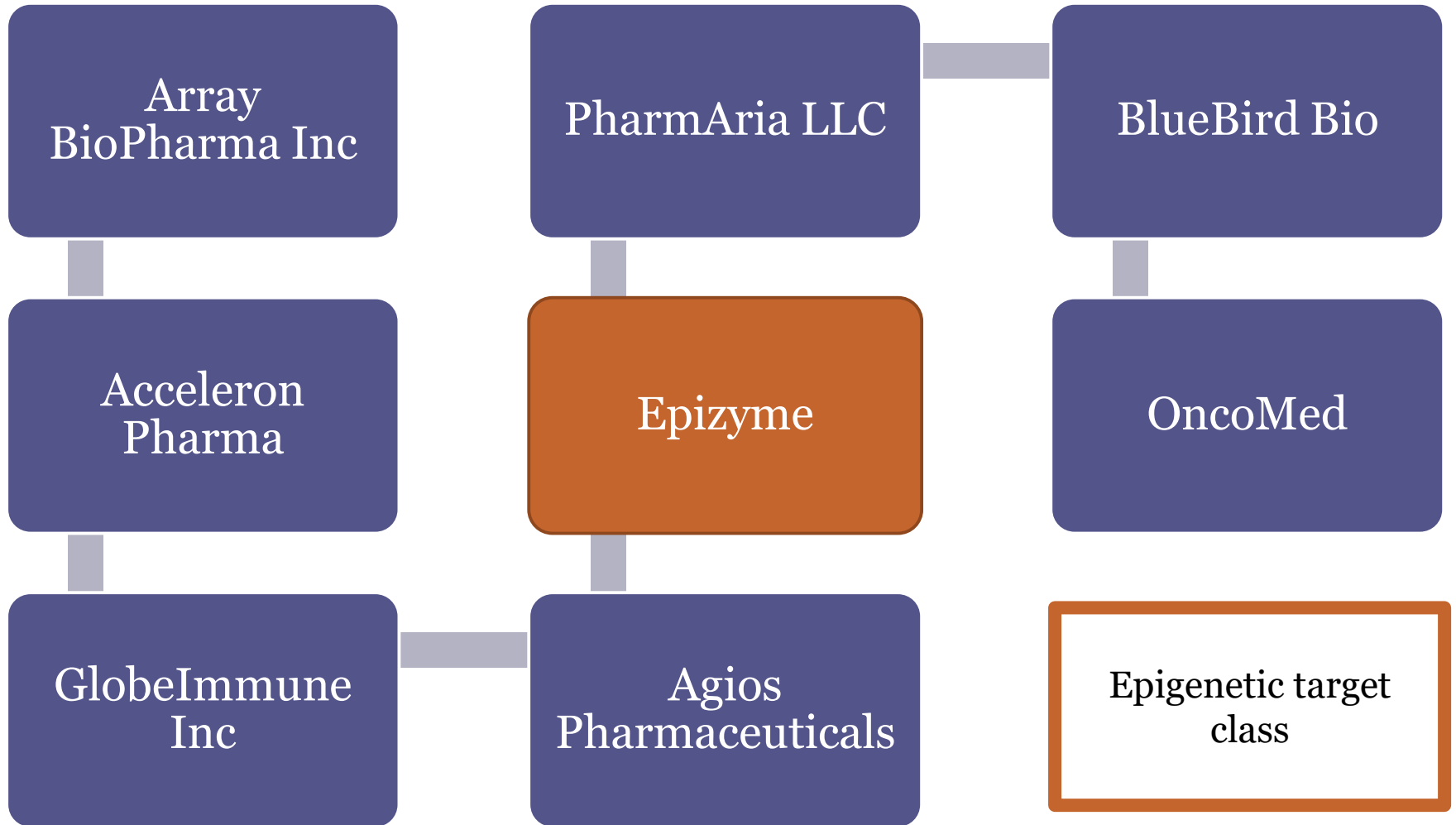
## 2. Alliances

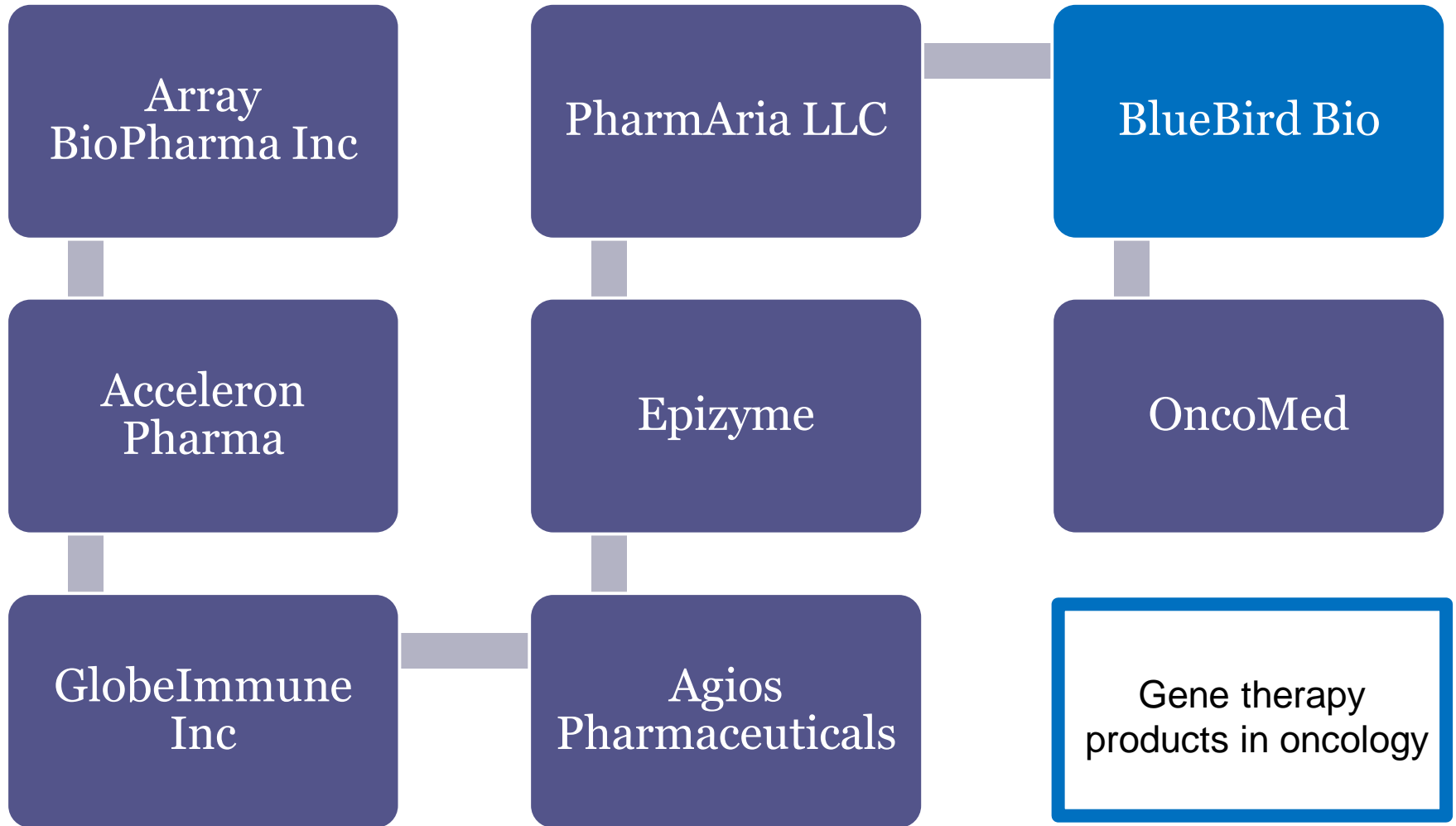
- With small development companies (promising candidates in pre-clinical /early stages)
- Shape future pipeline

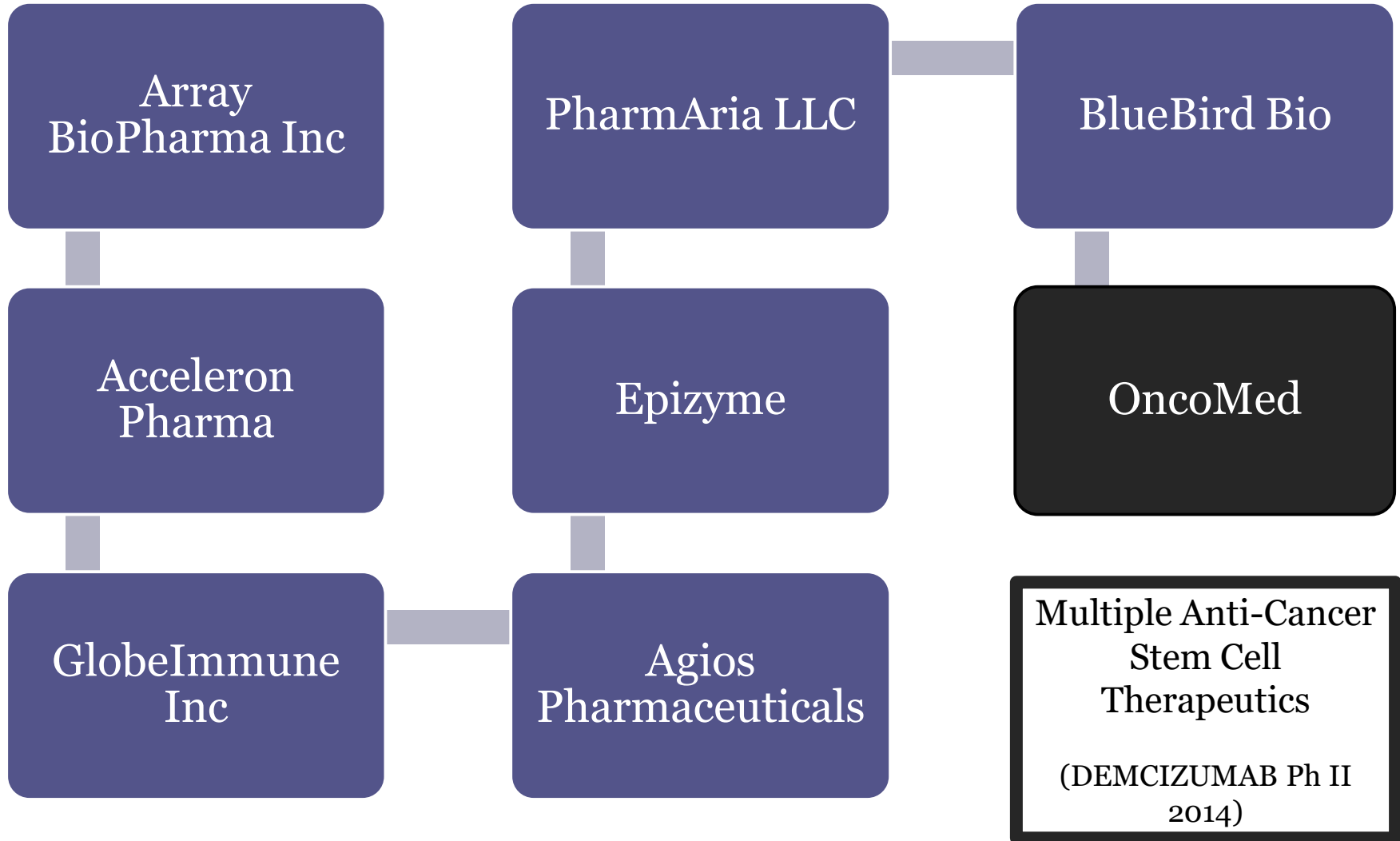












# Summary

Celanese Chemical Group spin-off

Biotech specialized in deracemization

The Thalidomide gamble

A simple but very efficient strategy

- Great clinical developments – OncoHematology & Inflammatory
- A controlled industrial protection, at all levels
- An abundant pipeline (early & late stages)
- Acquisitions allowing ready products
- Alliances allowing upcoming developments to be followed





# 4 - PERSPECTIVES



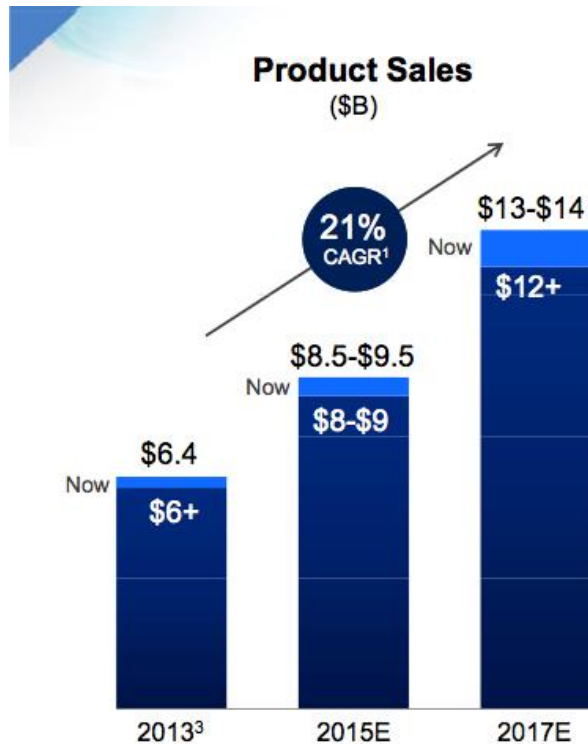
# Short term Perspectives – 2014/2015

- Approvals : Psoriatic Arthritis (1M patients) & Psoriasis (2.5M patients)

→ Otezla<sup>®</sup> (apremilast)

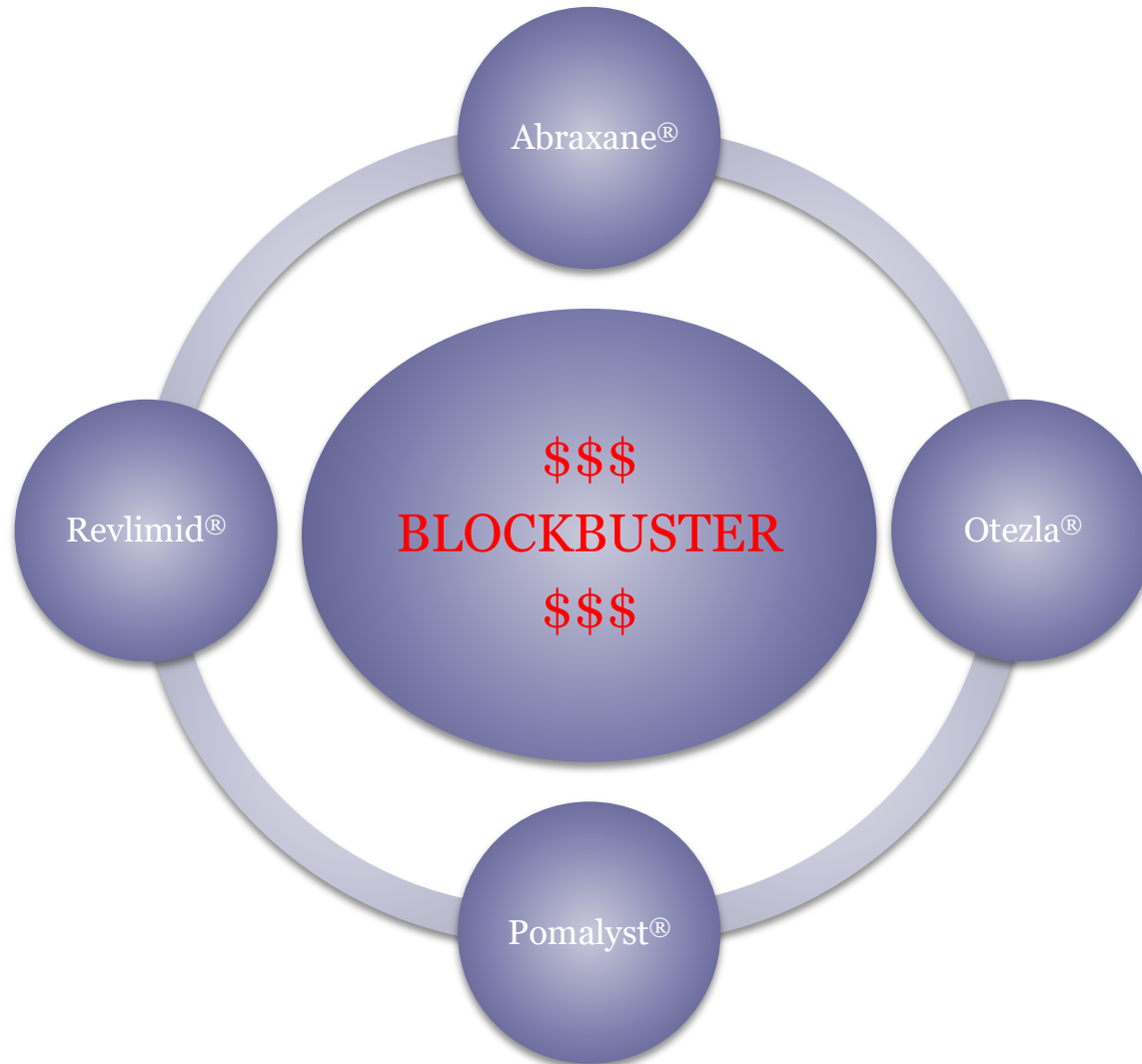
 <p>Swelling of Joints Due to PsA Psoriasis of Skin</p>	<p>Psoriatic Arthritis</p>	<p>~1.0M</p>
	<p>Psoriasis (moderate to severe)</p>	<p>~2.5M</p>

# Mid-term Perspectives – 2017



- +21% products sales between 2013 and 2017

# Mid-term Perspectives – 2017





# Availabilities

Thousands \$	2006	2007	2008	2009	2010	2011	2012
Total Revenue	898,873	1,405,820	2,254,781	2,689,893	3,625,745	4,842,070	5,506,713
Retained earnings	(101,773)	124,660	(1,408,993)	(632,246)	<b>248,266</b>	<b>1,566,416</b>	<b>3,022,596</b>

Source : Celgene

No dividend distributed

Investors dislike to many available and unused cash – They would prefer investments in future projects

Available cash allows :

- Immediate investments in clinical trials (otherwise the products goes back to partner company)
- Acquisitions of partner companies

# What are the next steps ?



- Continue on same line : acquisitions ?



# Kyprolis (Onyx)



- Onyx : « *the top biotechnology takeover target in 2012* »
- Kyprolis<sup>®</sup> acquired by Amgen in Aug. 2013 (\$10.4 B)
- Multiple Myeloma (3rd line) => Pomalyst<sup>®</sup> competitor
- Did Celgene think to buy Kyprolis<sup>®</sup> before Amgen?



# What are the next steps ?



- Continue on same line : acquisitions ?
- **Move towards a strategy of rupture ?**





# Stem Cells

- Acquisition of Anthrogenesis in 2002 for \$45M
- Collaboration with Oncomed in 2013 for \$155M + \$22.25M investment + \$790M milestones
- Human placental tissue stem cells → bone marrow transplants (hematological cancers)
- Also : LifeBankUSA<sup>®</sup> (cord blood bank – issued from Anthrogenesis acquisition)

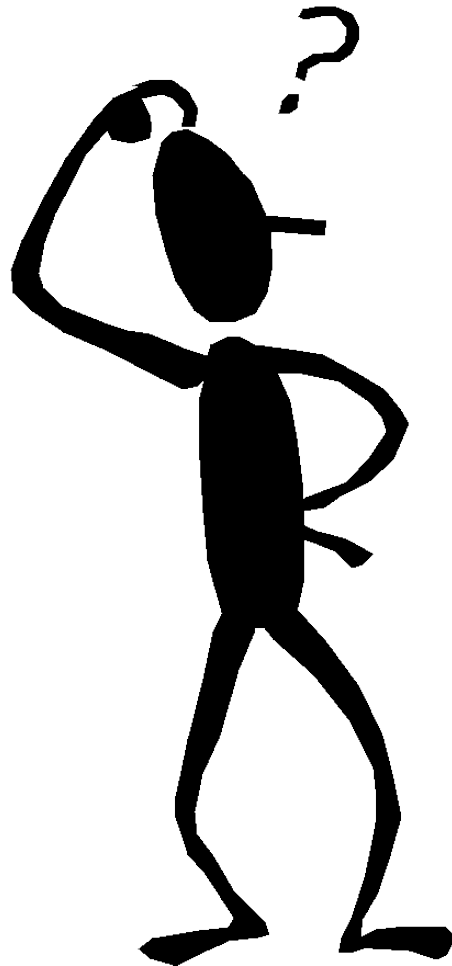


# Gene Therapy



- Epigenetics
- Collaboration : \$90M upfront + \$160M milestones (2012)
- Current products : Vidaza<sup>®</sup> / Istodax<sup>®</sup>
- Pipeline : CC-486 (solid tumors – ph II / AML – ph III)
- Collaborators : DOT1L (Leukemia – ph I)
- Diagnostic tools to identify genetic abnormalities

# Is Celgene still a biotech ?



# Today Celgene

✓ Association between *Life Sciences* and a set of *modern techniques*

✓ Innovation

✓ revenue invested in R&D ↘ ↘

✗ spirit of a small pharma

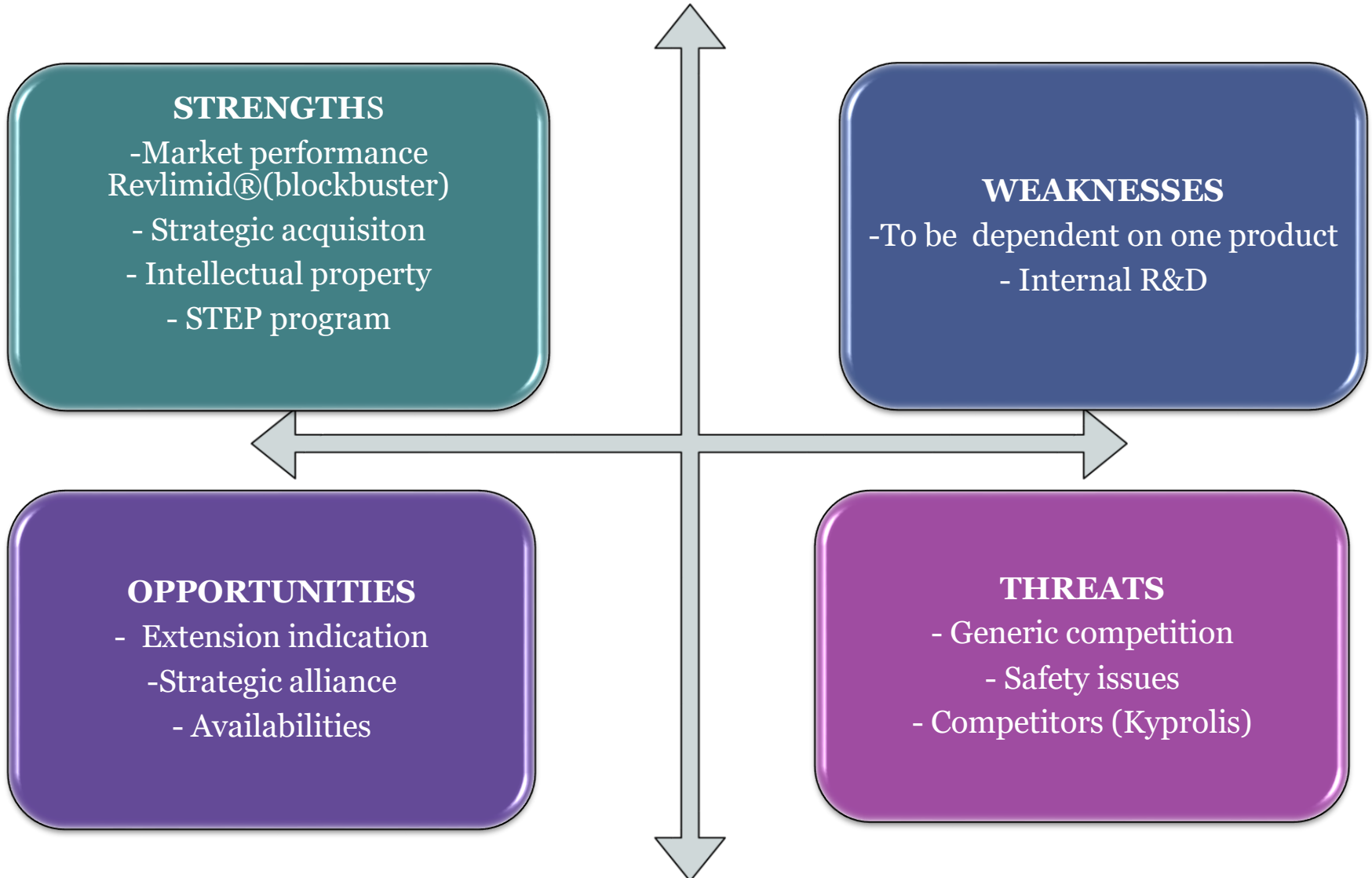
✗ losing money

→ BioPharmaceutical

# 5-CONCLUSION



# SWOT Investors





# Working at Celgene ?



Operational experience

Innovative therapies

Job opportunities



Risk taking

One product dependence

<a href="#">Associate Director, Regulatory Affairs Job</a>	Berkeley Heights, New Jersey, United States	Jan 15, 2014
<a href="#">Manager, Regulatory Affairs Job</a>	Mississauga Ontario Canada	Jan 13, 2014
<a href="#">Director, Regulatory Affairs, Brazil Job</a>		Jan 13, 2014
<a href="#">Associate Director, Regulatory Affairs Job</a>	Mississauga Ontario Canada	Jan 11, 2014
<a href="#">Drug Safety Specialist - 12 Month Contract Job</a>	Mississauga Ontario Canada	Jan 7, 2014
<a href="#">Associate Director, Regulatory Affairs Job</a>	Berkeley Heights, New Jersey, United States	Dec 20, 2013



# THANK YOU FOR YOUR ATTENTION



Committed to  
improving the  
lives of patients  
worldwide®