OmicsX
Intelligent BioSolutions

2013

ONCOLOGY INTELLIGENCE

A Comprehensive Report for Decision Making

Oncology COMPANIES | Cancer MOLECULES | Cancer INDICATIONS | Oncology MANAGEMENT | Profile CLINICAL | Profile PRECLINICAL

HH Biotechnologies Pvt. Ltd.

ONCOLOGY INTELLIGENCE

A Comprehensive Report for Decision Making 2013

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WORLDWIDE DISTRIBUTION OF CANCER CLINICAL PIPELINE COMPANIES

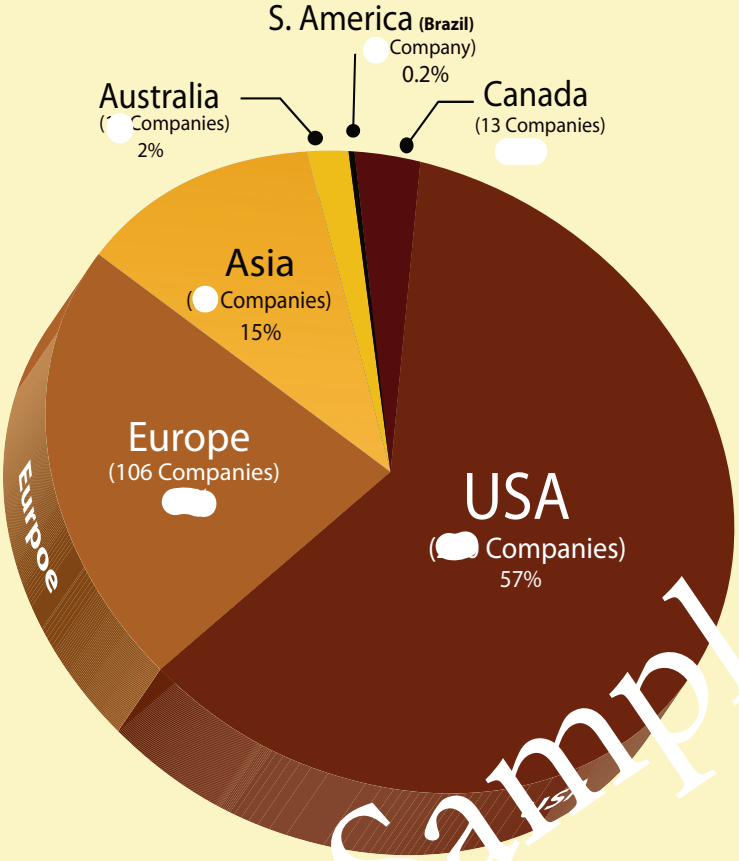
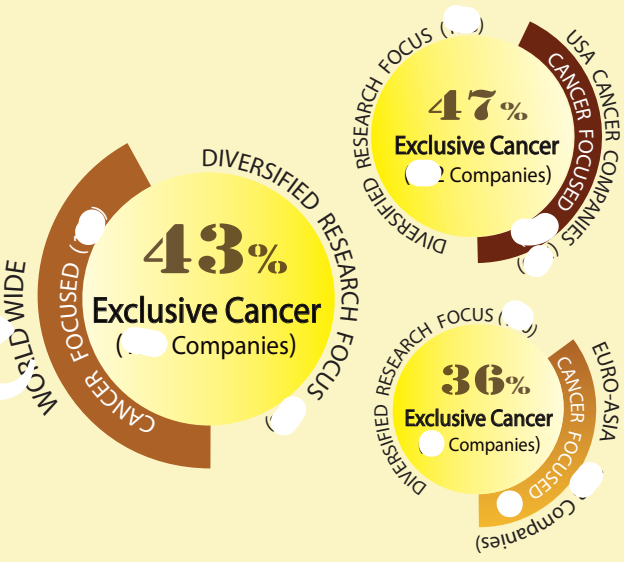


Fig A.1 **Global Distribution of Cancer Companies (with active clinical pipeline).**

Fig A.3 **Diverse vs. Exclusive Cancer Clinical Drug Development Companies.**



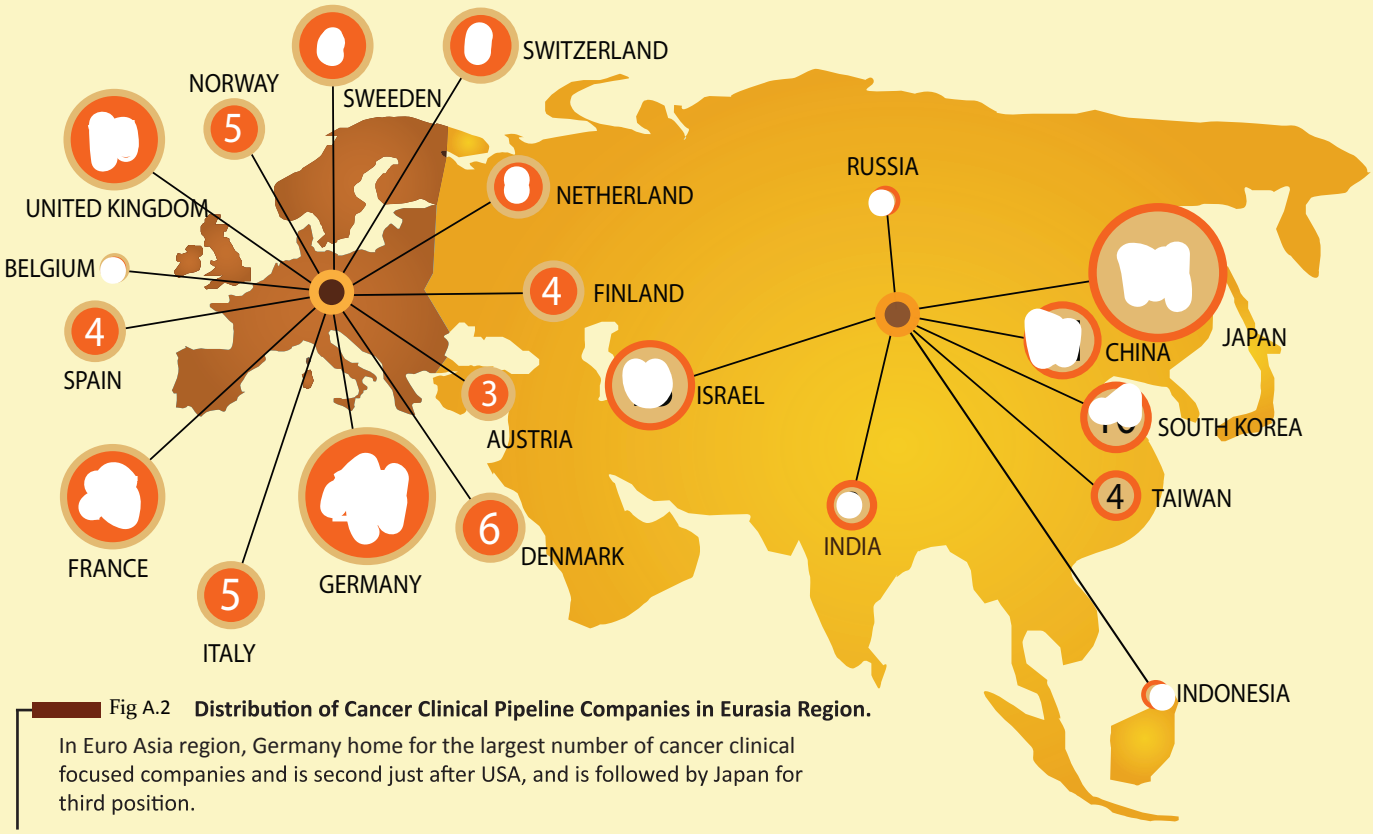


Fig A.2 **Distribution of Cancer Clinical Pipeline Companies in Eurasia Region.**

In Euro Asia region, Germany home for the largest number of cancer clinical focused companies and is second just after USA, and is followed by Japan for third position.

DIVISION OF CANCER CLINICAL COMPANIES ON THE BASIS OF HUMAN RESOURCE

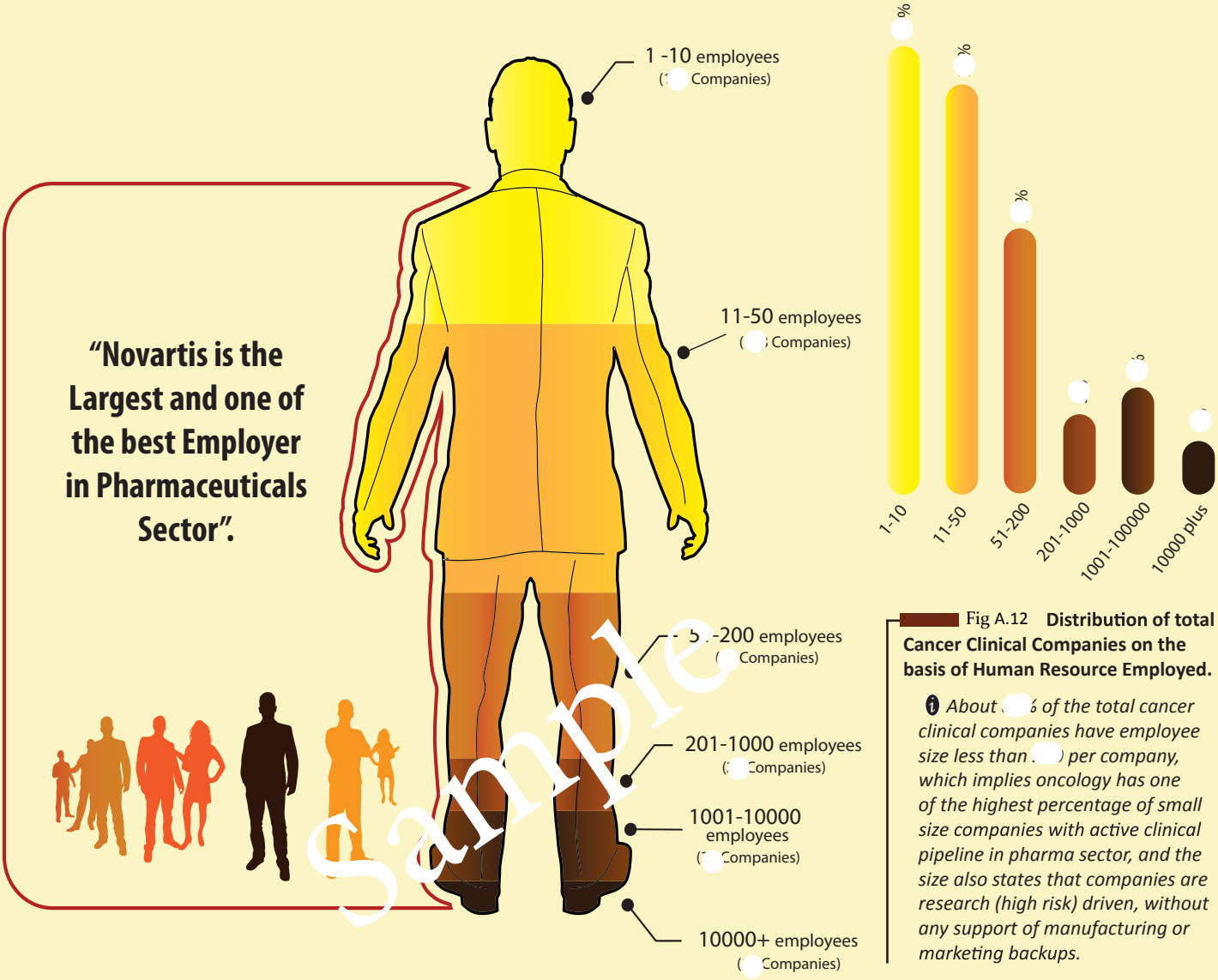


Fig A.12 **Distribution of total Cancer Clinical Companies on the basis of Human Resource Employed.**

About % of the total cancer clinical companies have employee size less than per company, which implies oncology has one of the highest percentage of small size companies with active clinical pipeline in pharma sector, and the size also states that companies are research (high risk) driven, without any support of manufacturing or marketing backups.

Top 10 cancer drug development companies (in terms of employee numbers)

Table No. A.1

	Company Name	Total Number Of Employee			Total Number Of R&D Staffs	
		2011	2010	2009	2011	201
1.	Novartis	123,686	119,418	99,834		
2.	Sanofi SA	113,719	101,575	104,867		
3.	Bayer AG	111,800	111,400			
4.	Pfizer	103,700	11			
5.	GlaxoSmithKline	97,38				
6.	Abbott Laboratories					
7.	Merck & Co.					
8.	Hoff-ma					
9.						
10.						

SECTION - A

INFOGRAPHICS

CLINICAL ONCOLOGY COMPANIES DISTRIBUTION IN UNITED STATES OF AMERICA

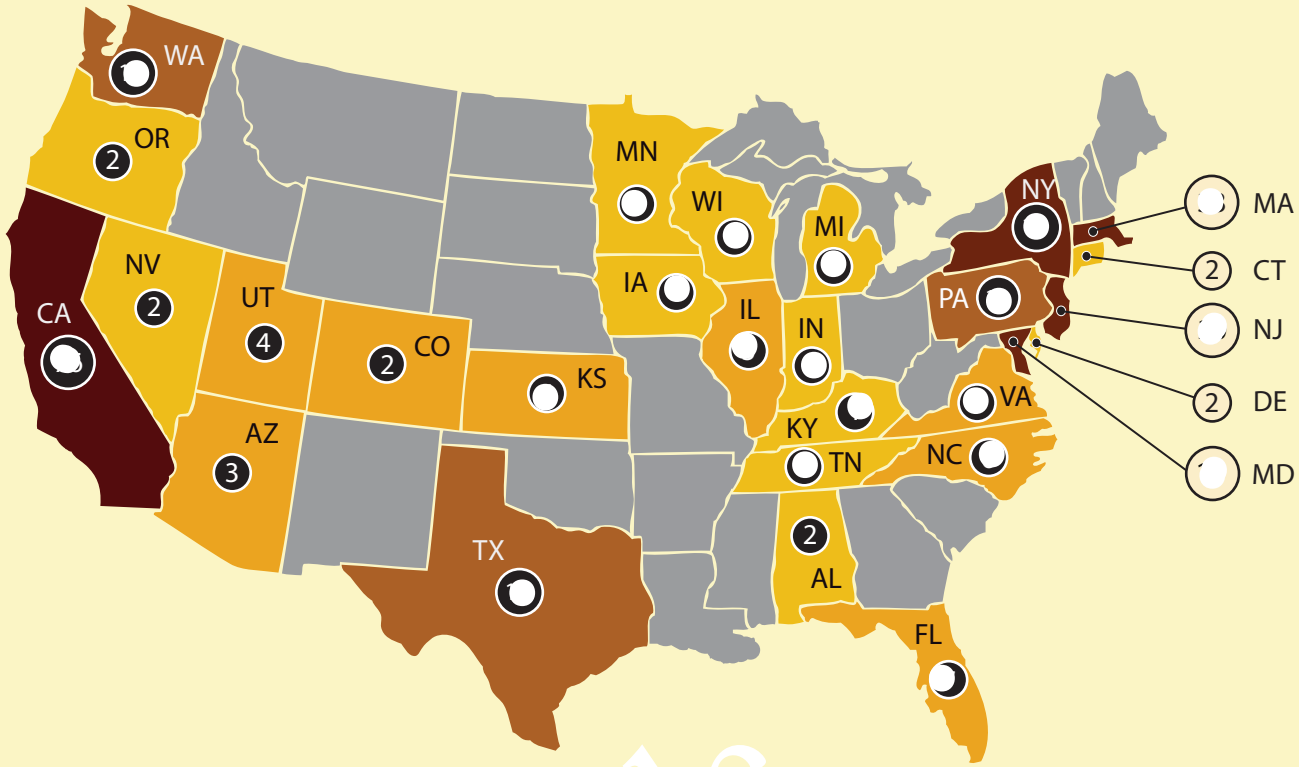
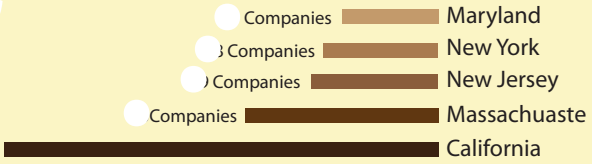
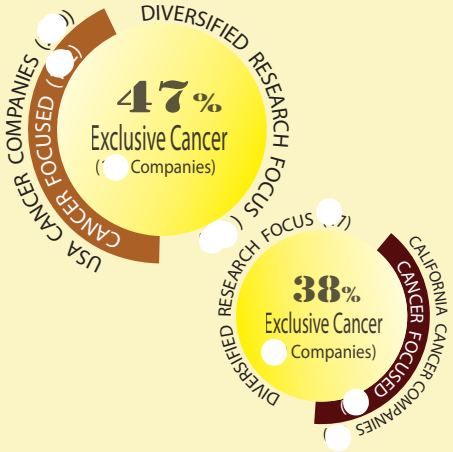


Fig A.13

A. Distribution of Cancer Clinical Companies with... different States of United States.



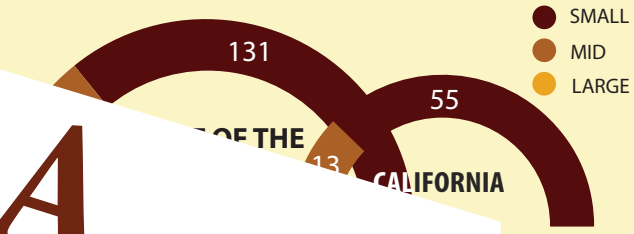
B. Top Five U.S.A States, wi... ...st ...mber of cancer clinical companies.



C. Exclusive/Diversified Cancer Clinical companies in U.S.A and California State.

SECTION - A

INFOGRAPHICS



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DISTRIBUTION OF ONCOLOGY MOLECULES IN CLINICAL DEVELOPMENT (1037 MOLECULES)

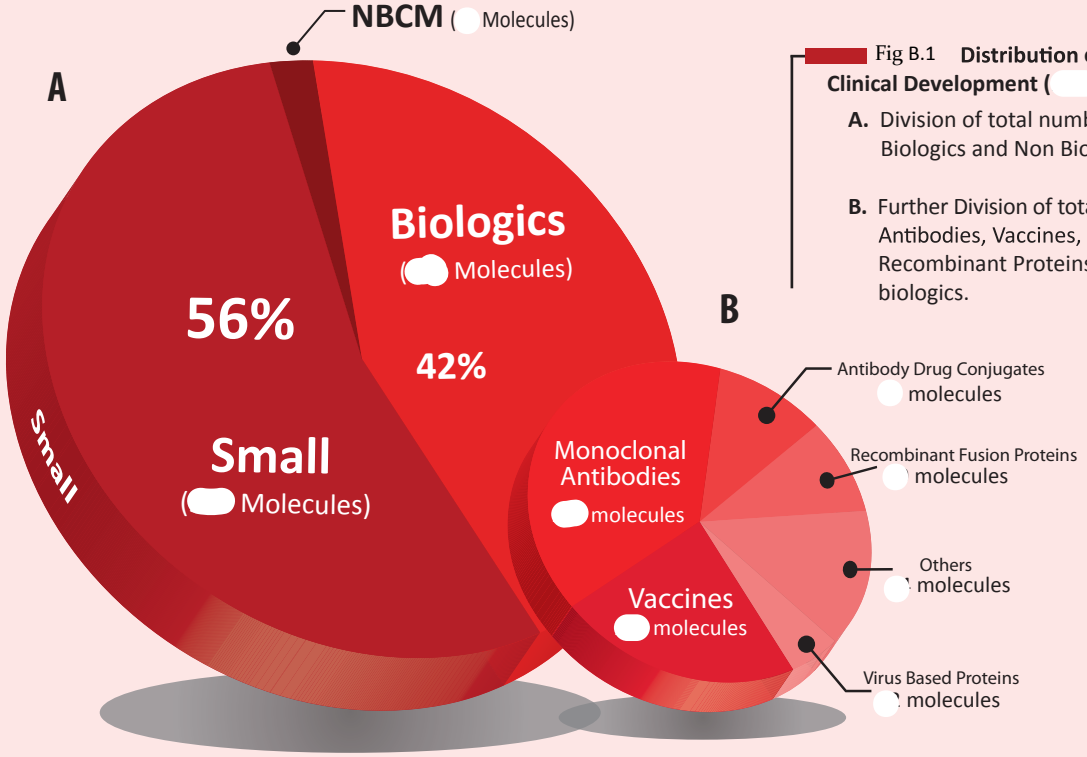


Fig B.1 Distribution of Oncology Cure Molecules in Clinical Development (Molecules).

A. Division of total number of molecules in Small, Biologics and Non Biologics Complex Molecules.

B. Further Division of total Biologics into Monoclonal Antibodies, Vaccines, Antibody Drug Conjugates, Recombinant Proteins, Gene Therapies and other biologics.

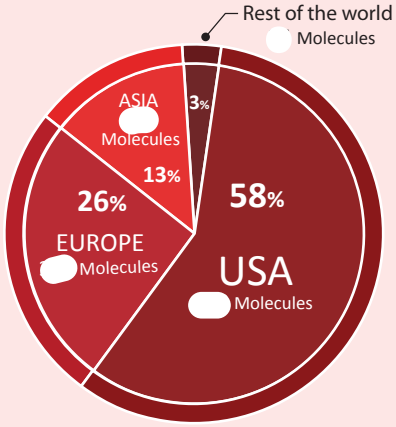


Fig B.2 Total number of cancer molecules in development in USA, Europe, Asia and Rest of the World.

Europe accounts for nearly of world's total cancer clinical companies, developing of total cancer clinical molecules, while USA is a home for nearly of total companies developing of total cancer clinical molecules.

SECTION - B
INFOGRAPHICS

Fig B.3 Molecule Development Strategies - Top companies *vs.* remaining companies.

Total molecules in development – Top
ies (in terms of numbers of cancer
al development) ***vs.***
ies.

prox. 2%
of

DISTRIBUTION OF ONCOLOGY INDICATIONS IN CLINICAL DEVELOPMENT

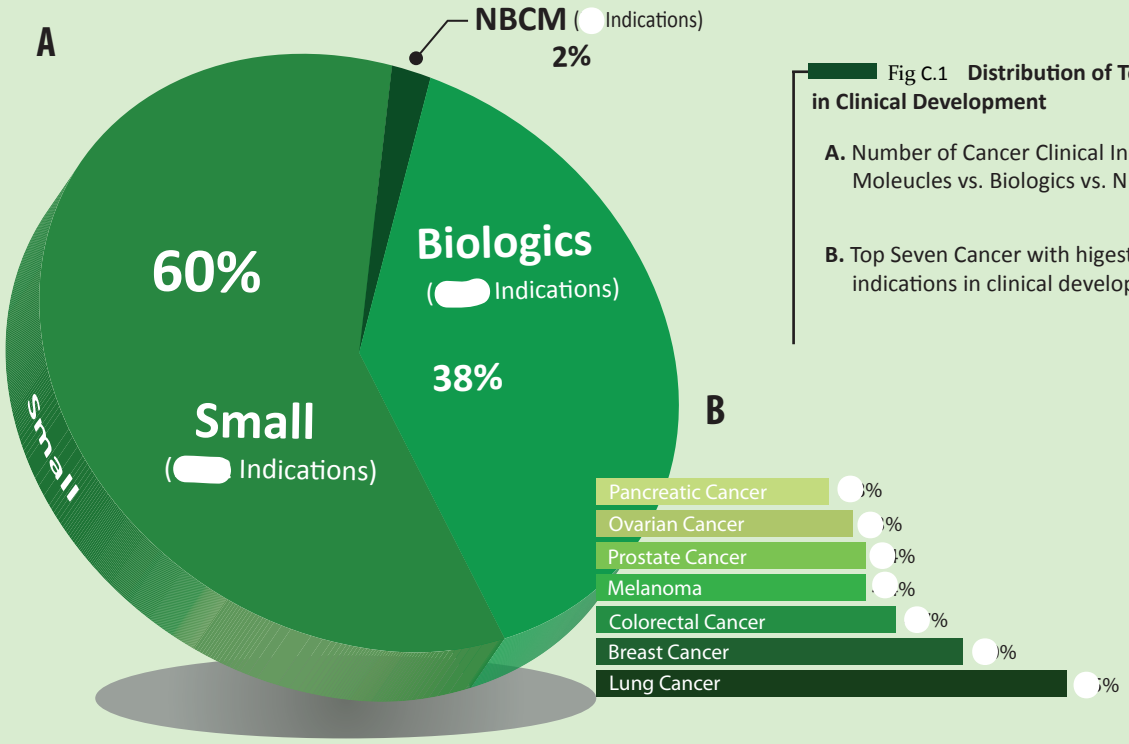


Fig C.1 **Distribution of Total Oncology Indications in Clinical Development**

A. Number of Cancer Clinical Indications for Small Moleucles vs. Biologics vs. NBCM.

B. Top Seven Cancer with higest number of molecules/ indications in clinical development.

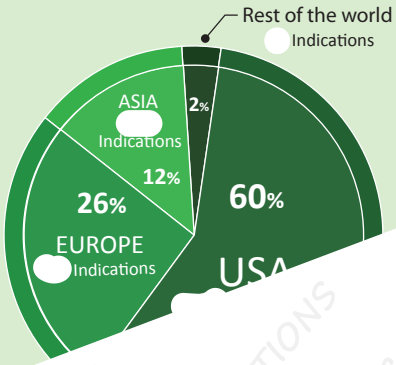
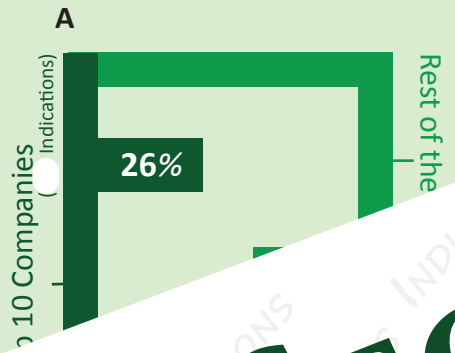


Fig C.2 **Distribution of Total cancer clinical iIndications in USA, Europe, Asia and RoW.**



SECTION - C

INFOGRAPHICS

CLINICAL DEVELOPMENT PROFILE – LUNG CANCER

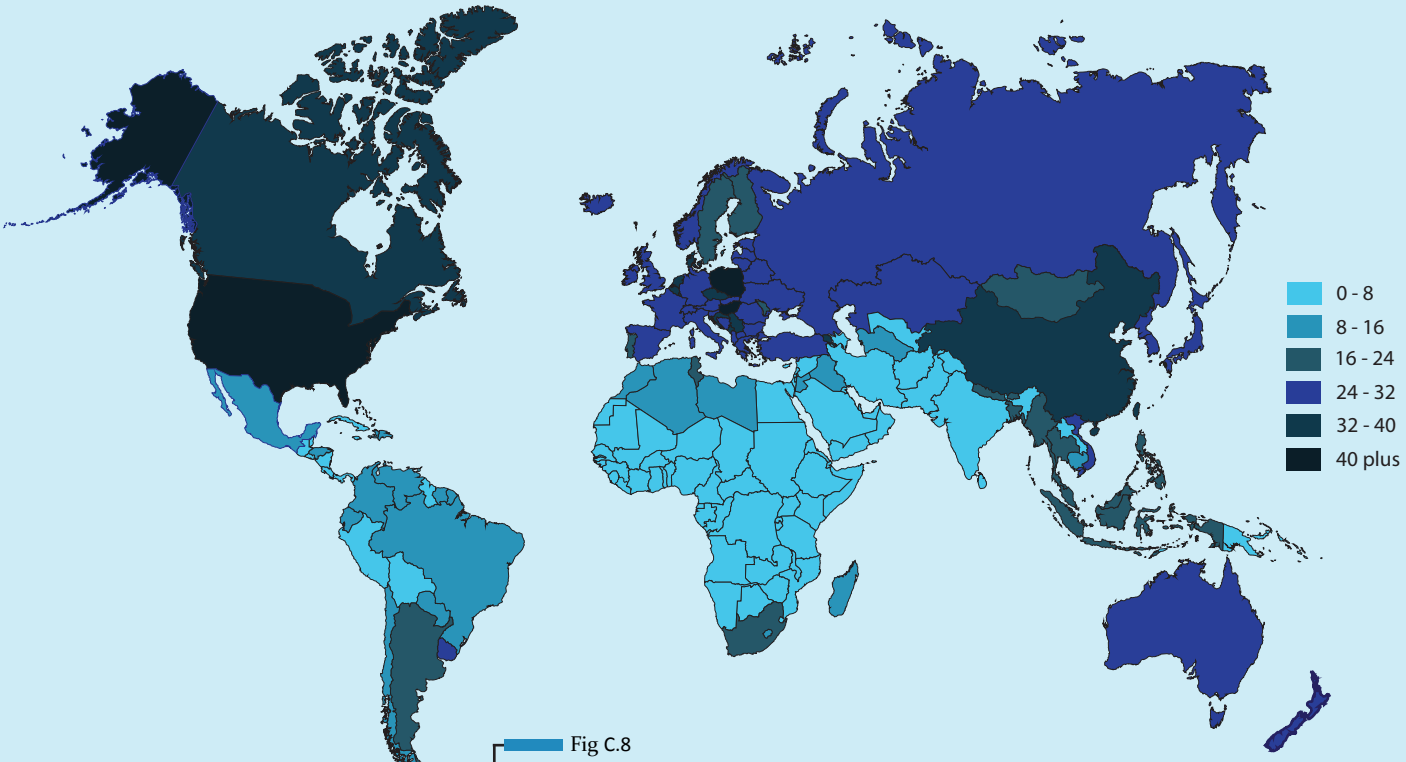


Fig C.8
Incidence of Lung Cancer (Age-Standardized Rates per 100,000)
Source: 2008 GLOBOCAN

➲ An Overview to Lung Cancer

Box No. C.1

Lung cancer is a disease characterized by uncontrolled cell growth in tissues of the lung. It can be broadly classified into two main types (based on the cancer's appearance under a microscope): non-small cell lung cancer and small cell lung cancer. Non-small cell lung cancer (NSCLC) accounts for 80% of lung cancers, while small cell lung cancer (SCLC) accounts for the remaining 20%.

Non-small cell lung cancer (NSCLC) is further divided into three sub types:

- ***Adenocarcinoma:*** Develops in phlegm (mucus producing) cells, lies in the lining of the airways and is most common subtype.
- ***Squamous Cell Carcinoma:*** Develops in the cells which line the airways, and is the second common (20-25%) subtype of NSCLC.
- ***Large Cell Carcinoma:*** It grows at an accelerated rate near the surface of Lung.

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Current & Forecast Epidemiology – United States of America

Lung cancer (NSCLC+SCLC) is the second most common cancer in both men and women (not counting skin cancer) and accounts for about

World Estimates:- According to GLOBOCAN 2008, an estimated 1.61 million new cases of lung cancer were diagnosed worldwide, accounting for about 13 per cent of total cancer cases diagnosed. It is the leading cause of cancer death world-wide in both men and women, with an estimated 1.4 million death each year.

Current Market Size & Forecast:

In Oct 2012 Abraxane was approved for NSCLC, and together with Xalkori (approved last year) can lift NSCLC market in 2013 which was sub[illegible]d in 201[illegible]2, due to [illegible]ent expir[illegible]f two key [illegible]gs Gemza[illegible]nd Taxote[illegible]. The NSC[illegible]drug mark[illegible]was estim[illegible]d at $4.2 [illegible]llion USD

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➲ Top Selling Chemotherapies for Lung Cancer

Table No. C.2

1.	**Pemetrexed/Altima®** *Eli-lilly*	A folate antimetabolite drug against NSCLC generated $2.46 billion USD compare to $2.20 Billion USD in 2010 (11% increase yoy).
2.	**Gemcitabine/Gemzar®** *Eli-lilly*	A nucleoside analog used as chemotherapy, achieved $452 Mn USD sales in 2011 compare to $1,149 Mn USD in 2010 due to patent expiry.
3	[illegible]xel[illegible]®	[illegible]ally [illegible]abli[illegible]mit[illegible]oth[illegible]d [illegible]ual $1[illegible] USD [illegible]om

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Top Selling Targeted Therapies for Lung Cancer

Table No. C.3

1.	**Bevacizumab/Avastin®** *Genentech/Roche*	humanized mAb that inhibits VEGF-A, and is used in first-line advanced nonsquamous NSCLC treatment in combination with chemotherapy. Total revenue generated by Bevacizumab for the year 2011 is $5.7 Bn USD.
2.	**fitinib/Ire ®**	is an EGFR K inhibitor at acts to ck signal r cancer rowth an urvival in CLC. Iress chieved

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Molecules in PH III Clinical Development for Lung Cancer (NSCLC)

Table No. C.4

	Name of Drug	Indications	Combination Drug	Line	Company	Partners	Target	Launch
1.	**Teysuno/TS-1** *	Advanced NSCLC	Docetaxel + Cisplatin	1st	**Taiho Pharm**	-		**Mid 2013**
2.	**Cetuximab/ Erbitux** @	EGFR-expressing Advanced NSCLC	Cisplatin/ Vinorelbine	1st	**ImClone**	BMS & Merck KGaA	EGFR	**Late 2013**
	\$	NS					β	

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Monoclonal Antibodies in Development

Table No. C.5

	Molecule	Target	Phase		Molecule	Target	Phase		Molecule	Target	Phase
1	Ipilimumab	CTLA4	III	13	RG7414	EGFL7	II	25	MM-121	ErbB3	I/II
2	tuzumab	-Met		14	P ab	25		26	Vol ab	1 integri	I

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Vaccines in Development

Table No. C.6

	Molecule	Target	Phase		Molecule	Target	Phase		Molecule	Target	Phase
1	TeloVac	-	III	5	HS-110	-	II	9	Hyper Acute lung	-	I/II
2	Stimuvax	MUC-1	III	6	PT 107	-	II	10	GSK2302032A	PRAME	
3		GF-β		7				11			

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Biologic in Development

	Molecule	Type	PH		Molecule	Type	PH	
1	Talactoferrin	Recombinant Protein	III	10	REOLYSIN	Reovirus	II	
2	GSK1572932A	Antigen-Specific Cancer unc ic	III	11	ADI-PEG 20	Pegylated arginine ina		

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Non Small Cell Lung Cancer (Clinical Pipeline)

Table No.

	Name of Drug	PH	Company	Partner	Target
1	**Ganetespib**	II/III	Synta Pharma	-	Hsp90
2	**TG4010**	II/III	Transgene	Novartis	-
3	nib	II	Abbo	G ch	VEGF

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SIMILAR PROFILES OF 19 CANCER INDICATIONS WHICH VIRTUALLY COVERS COMPLETE CANCER CLINICAL PROFILE

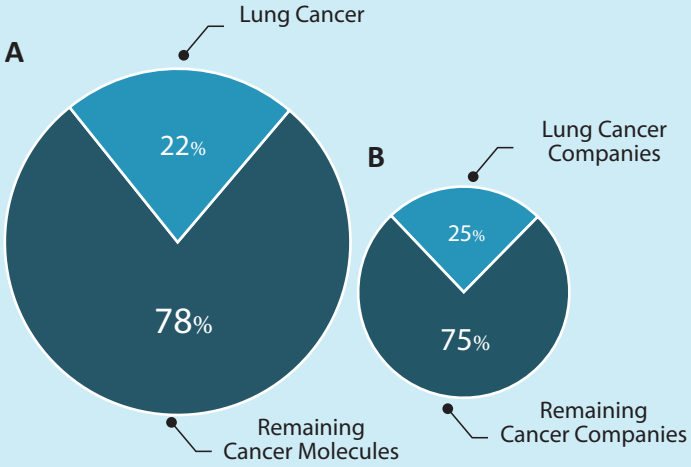

Fig C.9

A. Lung Cancer Cure Molecules in clinical development Vs. Total number of Molecules in Clinical development for cancer treatment, with defined indications.

B. Companies with active clinical development pipeline for Lung Cancer Treatment Vs. Total number of companies Worldwide, with active cancer cure clinical pipeline.

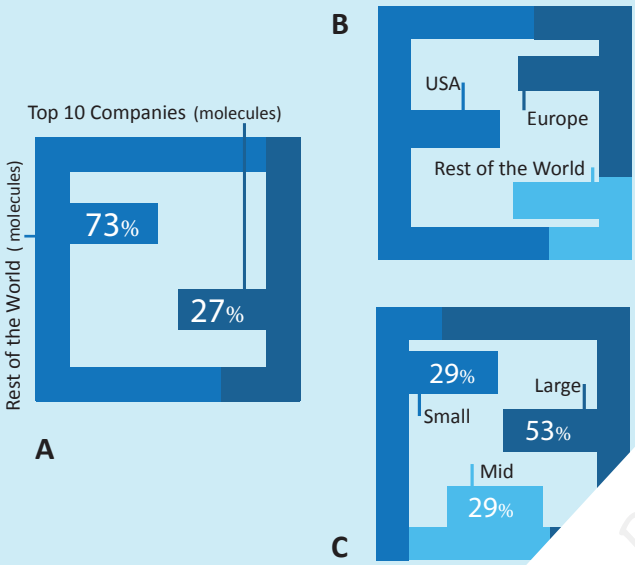

Fig C.10

A. A comparison between Top 10 Com
clinical pipeline Vs remaining co
To Learn More on Top 10 Co

B. Percentages of Molecule
Cancer cure between
Figure inside brack
corresponding r

C. Percentage
on the h

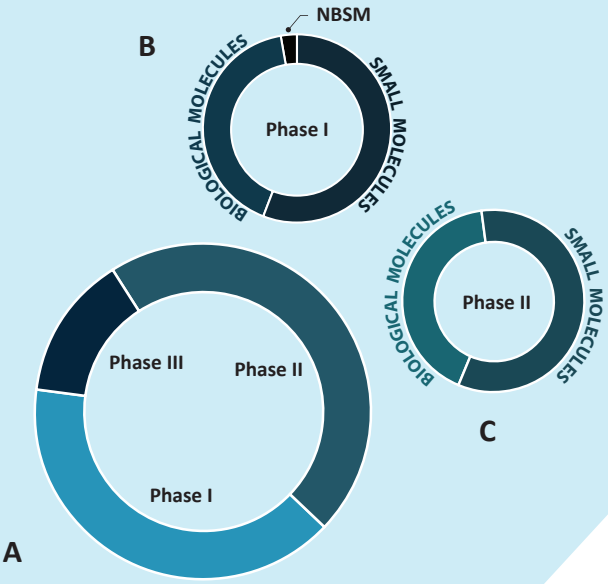

Fig C.11

A. Comparison between Top 10 Companies, Lur
clinical pipeline ***vs.*** remaining companies

B. Percentage of molecules in developr
between USA ***vs.*** Europe ***vs.*** RoW

C. Distribution of Lung Cancer
companies valuation size

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(8

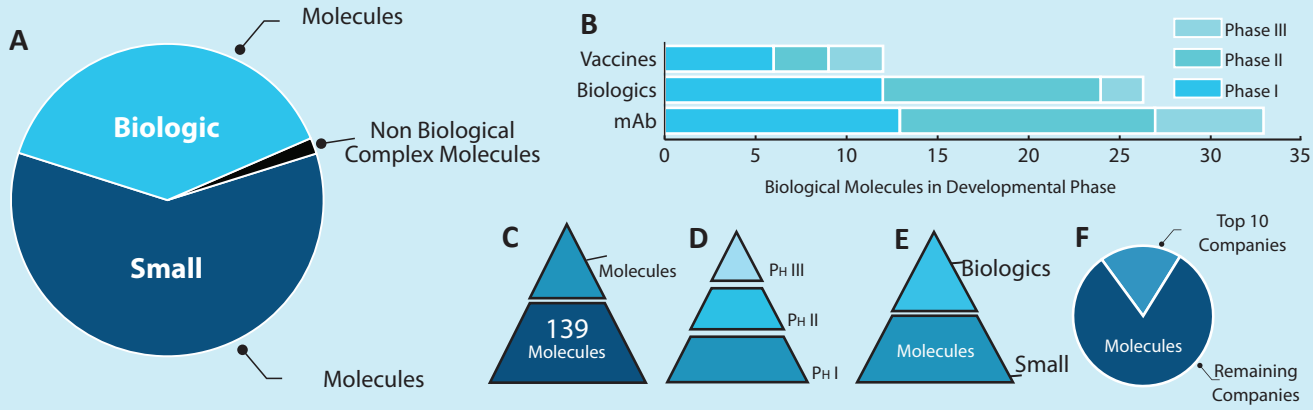

Fig C.12

A. Distribution of Lung Cancer clinical pipeline in *Small, Biologics & NBCM.*

B. Phase-wise distribution of *Vaccines, Monoclonal Antibodies* & other *Biologics.*

Molecules in partnering/collaboration ***vs.*** total number of molecules in development.

hase-wise distribution of partnering/collaboration molecules.

*ics **vs.** Small Molecules* in partnering/collaboration.

f molecules in partnering - Top 10 companies ***vs.*** remaining companies.

III Clinical Development for Lung Cancer (SCLC)

Table No. C.9

TIONS	COMBINATION DRUG	LINE	COMPANY	PARTNERS	TARGET	LAUNCH
Untreated, e Small-	Etoposide/Cisplatin	1st	**ChongKunDang Pharmaceutical**	ALZA Corp. & OnKor Pharma	Topoisomerase I	**Late 2013**
ll	Carboplatin + Etoposide	1st	**ZIOPHARM**	NC	DNA	**2016**
	poside/Platinum	1st	**BMS**	NC	CTLA4	**2017**

C.10

SMALL CELL LUNG CANCER (CLINICAL PIPELINE)

Table No. C.10

NAME OF DRUG	PH	COMPANY	PARTNER	TARGET
Ganitumab	I/II	Amgen	Millennium	IGF-1R
lotumumab	I/II	Amgen	-	Hepatocyte growth factor
000394	I/II	Bayer	-	CDK 1, 2, 4 and 9
omide	I/II	Celegene	-	TNF α
	I/II	Eli Lilly	-	Smoothened
	I/II	ImmunoGen	-	CD56
		Immunomedics	-	Carcinoembryonic antigen
		ck	-	HDAC
		um	-	Aurora A kinase
		a	Ono	20S proteasome
			-	SMO
				TOP1
				Smoothened
				GNA gangliosida GM3
				omerase 1

List of Orphan Drug Status

Table No. C.88

Drug Name	Phase	Indications	Developer	Narrations
NRC-AN-019	I	Glioma	NATCO Pharma Limited	US FDA
Mibefradil	I	Glioblastoma multiforme	Tau Therapeutics LLC	US FDA
SEPREHVIR®/HSV1716	I	Malignant Brain tumours	VIRTTU Biologics	EMEA
VAL-083	I/II	Glioma	DelMar Pharmaceuticals Ltd.	US FDA
Trans SodiumCrocetinate (TSC)	I/II	Glioblastoma multiforme	Diffusion Pharmaceuticals LLC	US FDA
[illegible]01	I/[illegible]	[illegible]ma	[illegible]nol	[illegible]FDA

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ONCOLOGY CLINICAL PIPELINE - NEW ENTRANTS 2012

➲ Molecules

Table No. C.89

	Name of Drug	Month	Company Name	Phase	Clinical Trial No.	Narrations
1.	Ensituximab/NEO-101	January	Neogenix Oncology	I/II	NCT01040000	Metastatic Pancreatic and Metastatic Colorectal Cancer
2.	CBLB502	January	Cleveland BioLabs	I	NCT01527136	Unspecified Adult Solid Tumor
3.	[illegible]axanabinol/ETS2101	January	[illegible]-Therapeutics plc	I	NCT01489826	Advanced Solid Tumours

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ONCOLOGY CLINICAL PIPELINE - MAJOR FAILURES 2012

➲ Molecules

Table No. C.90

	Name of Drug	Month	Company Name	Ph	Clinical Trial	Indications	Narrations
1.	Forodesine Hydrochloride/Immucillin	January	Mundipharma International	II	NCT01507467	Relapsed precursor T-Lymphoblastic Leukemia/Lymphoma.	Due to manufacturing issues.
2.	AFP464	January	Kirax Corporation	II	NCT01456325	ER+ Breast Cancer patients who had progressed on aromatase inhibitor therapy.	Recruiting or enrolling participants was halted prematurely.
3.	Saridegib/IPI-926	January	Infinity Pharmaceutical	II	NCT01522443	Previously untreated, metastatic Pancreatic Cancer.	Following preliminary analysis showing trial would not meet primary endpoint of overall survival.
4.	Trabedersen/ AP 12009	January	Antisense Pharma	III	NCT01546571	Recurrent Anaplastic Astrocytoma/Glioblatoma	Due to slow patient recruitment (no safety or efficacy issues).
5.	ZYBRESTAT/ Fosbretabulin	January	OXiGENE	II/III	NCT01579188	Anaplastic Thyroid Carcinoma	Due to inadequate funding.

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ONCOLOGY CLINICAL PIPELINE - MAJOR ADVANCES 2012

➲ Oncology Drug Molecules which Advances to Phase III during 2012

Table No. C.91

	Name of Drug	Month	Company Name	Phase	Clinical Trial No.	Narrations
1.	Nimoral/Nimorazole	January	Azanta A/S	III	NCT01507467	Squamous Cell Carcinoma of the Head and Neck
2.	Onartuzumab/MetMab/ RG3638/PRO143966	January	Genentech	III	NCT01456325	Met Diagnostic-Positive Non-Small Cell Lung Cancer Who Have Received Standard Chemotherapy for Advanced/Metastatic Disease
3.	Cabozantinib/ COMETRIQ™	January	Exelixis Inc	III	NCT01522443	Previously Treated Symptomatic Castration-resistant Prostate Cancer
4	[illegible]103A	[illegible]il	[illegible]olyne	III	[illegible]4657	Post-re[illegible]ion Melan[illegible] Patients [illegible] a High

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NEW DRUG APPROVALS - 2012

UNITED STATE FOOD AND DRUG ADMINISTRATION APPROVALS

Table No. D.1

	Company	Month	Collaboration	Proprietary Name	Established Name	Indications/Comments
1.	Genentech/Roche	January	Curis	Erivedge	Vismodegib	Treatment of adults with metastatic Basal Cell Carcinoma or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery and radiation.

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CORPORATE ACTIONS - 2012

MERGERS & ACQUISITIONS

Table No. D.2

	Acquirer	Month	Country	Target	Country	Deal Type	Deal Value (USD Mn)	Principal Focus / Description
1	Amgen	January	U.S.A	Micromet	U.S.A	Subsidiary	1,160	Phase 2/Biopharmaceuticals
2	Celgene	January	U.S.A	Avila Therapeutics	U.S.A	Merger	925	Phase 1/Biopharmaceuticals

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PARTNERING & COLLABORATIONS

Table No. D.3

	Company / Licensee	Month	Company / Licenser	Deal Type	Deal Value (USD Mn)	Upfront (USD Mn)	Principal Focus / Development Stage
1	Boehringer Ingelheim	January	FORMA Therapeutics	Collaboration	815	65	Discovery/Cancer
2	Janssen Biotech	January	FORMA Therapeutics	Collaboration	700	-	Discovery/Cancer
3	Boehringer Ingelheim	January	Priaxon	Collaboration	113	-	Discovery/Cancer

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ONCOLOGY MOLECULE / ASSEST ACQUISITION

Table No. D.4

	Acquirer	Month	Seller	Deal Type	Deal Value (USD Mn)	Upfront (USD Mn)	Comments
1	Kadmon Corporation	January	Concordia Pharma	Asset Purchase Agreement	Not Disclosed	Not Disclosed	Kadmon entered into an asset purchase agreement with Concordia Pharmaceuticals, under which Kadmon acquired all rights to Salirasib/ KD032, in PH II trial for the treatment of Non-Small Cell Lung Cancer.

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VENTURE FINANCING

Table No. D.8

	Company	Month	Raised (US Mn)	Financing Round	Investors
1	Apogenix	January	9.6	-	dievini Hopp BioTech; German Cancer Research Center; Apogenix's founders and management.
2	BerGenBio	January	8.8	Series A	Sarsia Seed; Investinor; Norsk Innoasjonkapital II; Birk Ventures; Meteva; Profond: Ro Invest; Sarsia Development

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Section - E

Individual 457 Oncology Clinical Company Profiles covered in 520 pages.

4SC AG

Cancer/Autoimmune Diseases

4SC AG

Am Klopferspitz 19a
82152 Planegg-Martinsried
Germany

www.4sc.de
manfred.groeppel@4sc.com
+49 897007630

Founded: 1997
Employee: 51-200
Ownership: Public
Valuation Size: Small

Highlights

- ★ 4SC AG is a biopharma company that discovers and develops targeted therapies for autoimmune and cancer indications.
- ★ 4SC uses chemoinformatic based technological platform (combining chemistry, biology with virtual High Throughput Screening technology, 4SCan®) for the development of new drug candidates.
- ★ In Jun 2008, 4SC AG acquired Nycomed's eight oncology projects ($19.7Mn USD) in preclinical and clinical developmental stages.
- ★ In Apr 2011, 4SC out-licensed developmental and marketing rights of Resminostat to Yakult Honsha Co for Japan.
- ★ In Dec 2011, 4SC forms subsidiary, 4SC Discovery GmbH to commercialise innovative early-stage drug research programmes.
- ★ In Jul 2012, 4SC AG entered into a research collaboration with Crelux GmbH and Ribological GmbH for the discovery and optimisation of anti-cancer drugs.

Products

Name	Target	Phase	Indication	Last Update	Molecule Type
Resminostat / 4SC-201	HDAC	I/II	Advanced Colorectal Cancer †	Mar 2012	Small Molecule
		II	Hodgking's Lymphoma *	Feb 2012	
		II	Hepatocellular Carcinoma *	Jun 2012	
4SC-203	FLT3/STK1, VEGFRs	I	Acute Myeloid Leukemia #	Jan 2011	Small Molecule
4SC-205	Eg5	I	Advanced Solid Tumors †	Apr 2012	Small Molecule
		I	Malignant Lymphomas †	Apr 2012	
4SC-202	class I HDAC	I	Advanced Hematological Malignancies †	Jul 2012	Small Molecule

Key Highlights Of Molecules

- ★ Resminostat is an oral pan-histone-deacetylase inhibitor that modifies DNA structure of tumor cells to cause apoptosis.
- ★ Resminostat has been granted for Orphan Drug status from US FDA and EMA for hodgkin's lymphoma.
- ★ 4SC-203 is a multi target kinase inhibitors (including FLT3, FLT3 mutants and VEGF- receptors).
- ★ 4SC-203 was jointly developed with ProQinase GmbH, a company based in Freiburg, Germany.
- ★ 4SC-205 is an oral inhibitor of kinesin spindle protein Eg5 (kinesin-5, KIF11), motor protein important for cell division (mitosis).
- ★ 4SC-202 is a benzamide type selective inhibitor of human class I HDAC isoenzymes 1, 2 and 3.
- ★ 4SC-207, a cell cycle blocker, is being evaluated in preclinical stage for the treatment of tumors resistance to chemotherapy.
- ★ 4SC acquired 4SC-201, 4SC-203, 4SC-202, 4SC-205 & 4SC-207 along with a portfolio of cancer compounds from Nycomed.

Corporate Profile

Thomas Werner, *Chairman*
Ulrich Dauer, *Chief Executive Officer*
Daniel Vitt, *Chief Scientific Officer*
Bernd Hentsch, *Chief Development Officer*

Listed / Not Listed:	Listed
Stock Code:	VSC
Stock Exchange:	Xetra
Market Capitalization:	146.19 (Mn USD) as on 14/12/12

† *Active, Recruiting* * *Active, Non-Recruiting* # *Completed* Trial status as on Dec 2012

Section - F

Individual 137 Exclusive Oncology Preclinical Company Profiles covered in 83 pages.

Armour Therapeutics Inc.

Cancer

124 Orchard View Bivd.,
Toronto, ON M4R 1C2,
Canada

www.armourtherapeutics.com
info@armourtherapeutics.com
+1 647-205-4402

Founded: NA
Employee: 1-10
Ownership: Private

Highlights

- Armour is a biopharma company developing therapies targeting hormonal pathway for the treatment of cancer.
- Its drug discovery is based on creating *first-in-class* relaxin receptor antagonists that block relaxin stimulated tumor and blood vessel growth and function as an anti-relaxin therapy.
- Armor's lead candidate AT-001 targets a new hormonal (non-androgen) pathway and suppresses tumor growth like a cytostatic and as an anti-angiogenic agent.
- AT-012 and AT-027 are in discovery phase for treatment of breast and ovarian cancer respectively.

Products

Name	Target	Phase	Indication	Molecule Type
AT-001	Relaxin	Preclinical	Prostate Cancer	Small Molecule

Corporate Profile

Josh Silvertown, Founder & *Chief Executive Officer*
George N. Nikopoulos, *Director, Business Development*
Anton Neschadim, *Director, Drug Development*

Listed / Not Listed: Not Listed
Stock Code/Exchange: NA
Market Capitalization: NA

Ascepion Pharmaceuticals, Inc.

Diversified

2nd Floor, Building C,
68 Xinqing Road,
Suzhou Industrial Park, China

www.ascepion.com
ascepionhr@ascepion.com
+86 512 62956001

Founded: 2007
Employee: 11-50
Ownership: Private

Highlights

- Ascepion is a biopharmaceutical company, developing molecular targeted therapies for the treatment of cancer.
- In Jun 2012, Ascepion and Debio Group entered into an exclusive worldwide license agreement, for the development and commercialisation of ASP-08126/Debio 1144.
- ASP-08126, ASP-502D & ASP-08112 are small molecule tyrosine kinase inhibitors, currently in preclinical stage of development for various cancer treatment.
- Key investors include: Kai-Feng Venture Capital and China-Singapore Suzhou Industrial Park Ventures Co., Ltd. (CSVC).

Products

Name	Target	Phase	Indication	Molecule Type
ASP-08126 / Debio 1144	Multikinase	Preclinical	Solid Tumors	Small Molecule
ASP-502D	Tyrosine Kinase	Preclinical	Cancer	Small Molecule
ASP-08112	Tyrosine Kinase	Preclinical	Cancer	Small Molecule

Corporate Profile

Shan Jiang, *Chairman & Chief Executive Officer*
Max Qian, *Chief Biologist*
Shirley S. Lei, *Chief Operating Officer*

Listed / Not Listed: Not Listed
Stock Code/Exchange: NA
Market Capitalization: NA

DEVELOPED & MARKETED BY:

HH BIOTECHNOLOGIES PRIVATE LIMITED
BioTech Park
Sector-G, Jankipuram, Lucknow
INDIA

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