

# Osteoporosis

Osteoporosis is a systematic skeletal disease characterized by low bone mass, increase of bone fragility and susceptibility to fracture.

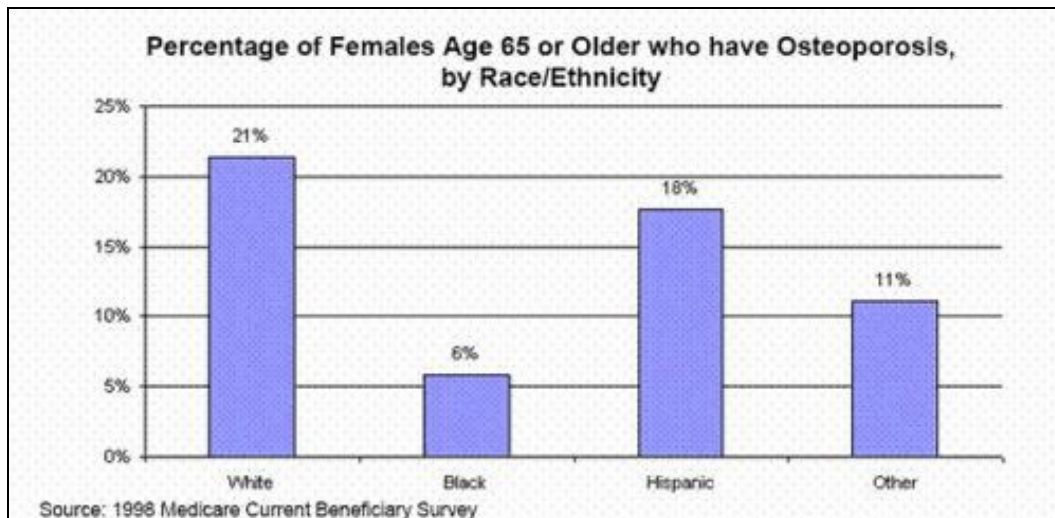
## Types of Osteoporosis and its causes

1. **Primary osteoporosis (Type I (postmenopausal) or Type II (senile)) :**
  1. *Type I (postmenopausal)*: Generally develops in women after menopause when the amount of estrogen in the body greatly decreases. This process leads to an increase in the resorption of bone (the bones lose substance).
  2. *Type II (senile)*: This involves a thinning of both the trabecular bone (the spongy bone inside of the hard cortical bone) and the hard cortical bone. This process often leads to hip and vertebral body (in the spine) fractures.
2. **Secondary osteoporosis**: Secondary osteoporosis has the same symptoms as primary osteoporosis. However, it occurs as a result of having certain medical conditions, such as hyperthyroidism or leukemia. It may also occur as a result of taking medications known to cause bone breakdown, such as oral or high-dose inhaled corticosteroids (if used for more than 6 months), too high a dose of thyroid replacement, or aromatase inhibitors (used to treat breast cancer).
3. **Osteogenesis imperfecta**: Osteogenesis imperfecta is a rare form of osteoporosis that is present at birth. Osteogenesis imperfecta causes bones to break for no apparent reason.
4. **Idiopathic juvenile osteoporosis**: Idiopathic juvenile osteoporosis is rare. It occurs in children between the ages of 8 and 14 or during times of rapid growth. There is no known cause for this type of osteoporosis, in which there is too little bone formation or excessive bone loss.

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## Incidence and prevalence



## Incidence

- 1 in 3 women over 50 will suffer a fracture due to osteoporosis; this increases to 1 in 2 over 60.
- 1 in 5 men over 50 will suffer a fracture due to osteoporosis; this increases to 1 in 3 over 60.
- Approximately 1.6 million hip fractures occur each year worldwide, the incidence is set to increase to 6.3 million by 2050.
- The highest risk of hip fractures are seen in Norway, Sweden, Iceland, Denmark and the USA.
- Currently, there is an increasing incidence of hip fractures in the developed cities in Asia. 1 out of 4 hip fractures occur in Asia and Latin America. This number of hip fractures will increase to 1 in 2 by 2050.
- In the Middle East, the burden of osteoporosis in the general population is expected to increase and is becoming a heavy financial burden.
- The annual incidence rate of osteoporotic fractures in women is greater than the combined incidence rates of heart attack, stroke and breast cancer. ([International osteoporosis foundation](#))

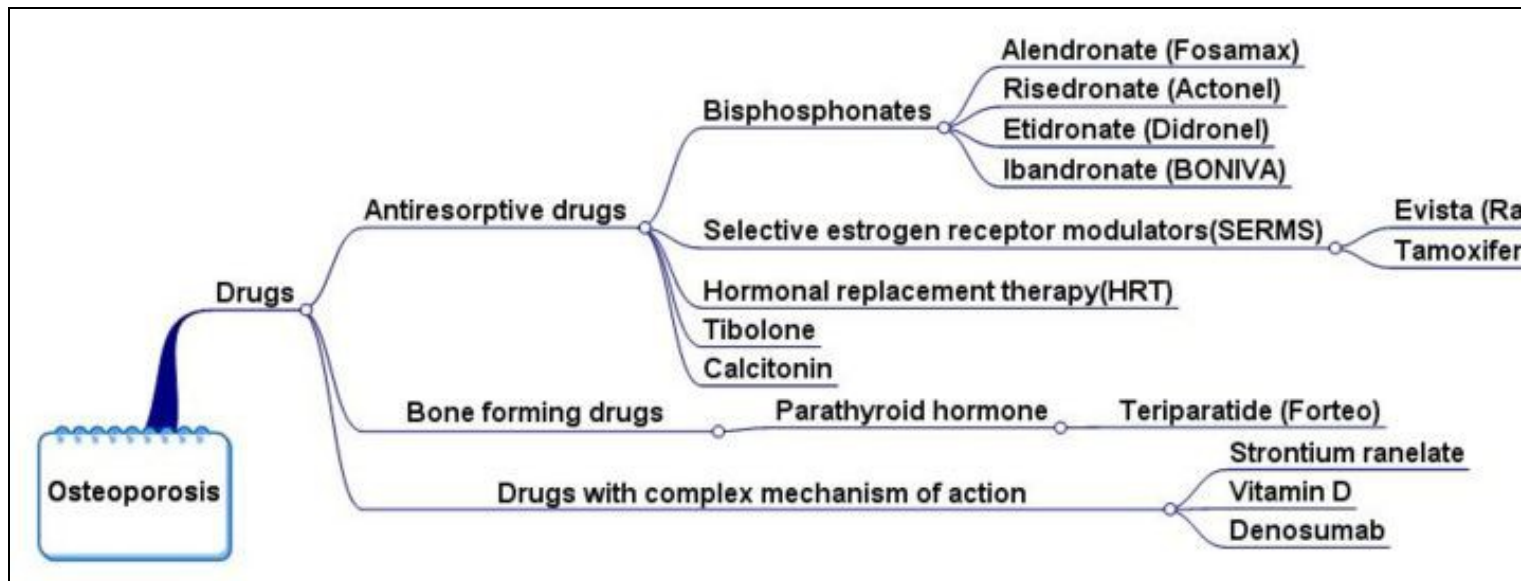
## Prevalence

- 28 million Americans (10 million with osteoporosis; 18 million with low bone mass); eight million American women and 2 million men (NWHIC)(approx 1 in 9 or 10.29% or 28 million people in USA).
- Total prevalence rate of osteoporosis in the middle-aged and elderly in China was 16. 1% in 2002. The prevalence rate among males was 11. 5% and among females was 19. 9%.
- Prevalence increase to 2.2 million in 2006 and 3 million in 2021 in Australia.

- The prevalence of Khon Kaen (Thai rural area) women has osteoporosis in femoral neck and lumbar spine is 19.3% and 24.7% respectively. (International osteoporosis foundation)

S.NO	Country/Region	Extrapolated Prevalence
1	USA	10 million cases (80% cases are women and 20% cases are men)
2	Australia	2.2 million
3	Middle east	18,603,593
4	Africa	47,233,590
5	Asia	359,862,754
6	Europe	80,590,570

## Product Information



Overall categorization of osteoporosis treatments

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## Products in market

Generic	Brand	Current Status	Type	Company
<b>Antiresorptives</b>				
<b>Bisphosphonates</b>				
Alendronate	FOSAMAX®	Approved by US	Postmenopausal	<a href="#">Merck</a>
Risedronate	Actonel®	Approved by US/ES	Postmenopausal	<a href="#">Sanofi-Aventis/Procter &amp; Gamble</a>
Ibandronate	Boniva?	Approved by US	Postmenopausal	<a href="#">Roche</a>
Etidronate	Didronel	Off Label		<a href="#">Procter And Gamble</a>
Zoledronic Acid	Aclasta	Approved	Postmenopausal	<a href="#">Novartis</a>

Selective Estrogen Receptor Modulators				
Raloxifene	Evista®	Approved by US	Osteoporosis	<a href="#">Eli Lilly</a>
Hormone Replacement Therapy				
Conjugated estrogen	Premarin®	Approved by US	Postmenopausal	<a href="#">Wyeth</a>
Conjugated estrogen	Cenestin?	Approved by US	Postmenopausal	<a href="#">Duramed</a>
Esterified estrogens	Estratab®	Approved by US	Postmenopausal	<a href="#">Solvay</a>
Esterified estrogens	Menesta	Approved by US	Postmenopausal	<a href="#">Monarch</a>
Estradiol Transdermal System	Menostar	Approved by US	Postmenopausal	<a href="#">Bayer</a>
Estradiol Transdermal System	Vivelle Dot	Approved by US	Postmenopausal	<a href="#">Noven</a>
Estradiol	Estrace®	Approved by US	Postmenopausal	<a href="#">Bristol-Myers Squibb</a>
Estradiol	Gynodiol	Approved by US	Postmenopausal	<a href="#">Novavax</a>
Tibolone	Livifem		Postmenopausal	
Calcitonin				
Calcitonin Salmon Injection	Miacalcin®	Approved by US	Postmenopausal	<a href="#">Novartis</a>
Calcitonin Salmon Nasal Spray	Miacalcin®	Approved by US	Postmenopausal	<a href="#">Novartis</a>
Calcitonin Salmon Nasal Spray	Fortical®	Approved by US	Postmenopausal	
Bone Forming Drugs				
Teriparatide	Forteo®	Approved by US	Osteoporosis	<a href="#">Pfizer</a>
Drugs with Complex Mechanisms of Action				
Strontium Ranelate	Protelos	Not approved in USA	Postmenopausal osteoporosis	<a href="#">Servier</a>
Vitamin D				
Calcium		<a href="#">FDA is considering amending rules so that companies can now claim that calcium and Vitamin D in their food supplements can prevent osteoporosis in all ages and both sexes</a>		FDA

## Product pipeline

Product Pipeline				
DRUG	COMPANY	DESCRIPTION	STAGE	
RANKL Inhibitors				
Denosumab	<a href="#">Atlantos, Amgen</a>	A monoclonal antibody	3	
Bisphosphonates				
Minodronate (YM529)	Astellas	Nitrogen containing bisphosphonate		
Calcium Antagonist				
423557	<a href="#">Glaxosmithkline</a>		1	
423562	<a href="#">Glaxosmithkline</a>		1	
Calcilytics (751689)	<a href="#">NPS and Glaxosmithkline</a>	Calcilytics antagonize calcium receptors on parathyroid glands resulting in a transient release of the body's own stores of parathyroid hormone (PTH).	1	

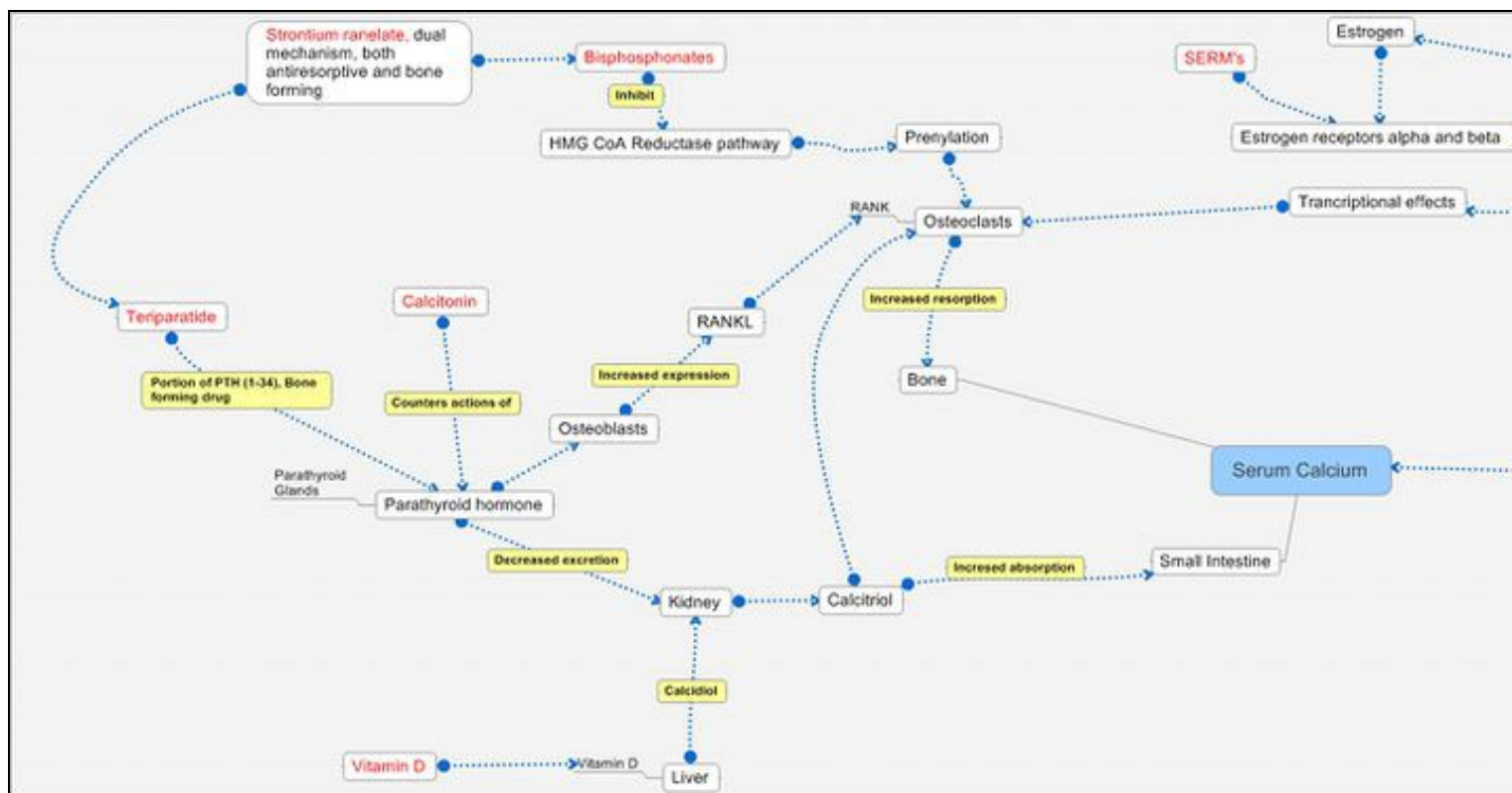
<b>Parathyroid Hormone</b>			
768974	<a href="#">Glaxosmithkline</a>	Parathyroid Hormone Agonist	1
Preos (rDNA origin)	<a href="#">NPS</a>	Recombinant Parathyroid Hormone	Registration Filed
PTH1-34	<a href="#">Nastech</a>	Intranasal Parathyroid hormone	2
PTH1-34	<a href="#">Novartis, Emisphere</a>	Oral Parathyroid hormone	1
PTH Analogs	<a href="#">Unigene</a>		2
<b>Cathepsin k Inhibitor</b>			
Relacatib (SB-462795)	<a href="#">GlaxoSmithkline</a>		1
AAE581	<a href="#">Novartis</a>		
MK-0822	<a href="#">Canadian Institutes of Health Research, Merck</a>		2
<b>Selective Estrogen Receptor Modulators</b>			
Bazedoxifene	<a href="#">Wyeth, Ligand</a>	A Third-Generation Selective Estrogen Receptor Modulator for Treatment of Postmenopausal Osteoporosis	
Lasofoxifene (Oporia)	<a href="#">Pfizer, Ligand</a>	A Third-Generation Selective Estrogen Receptor Modulator for Treatment of Postmenopausal Osteoporosis	NDA
Arzoxifene	<a href="#">Eli Lilly</a>		
Taromifene (Fareston)	<a href="#">Orion</a>		
<b>Calcitonin</b>			
	<a href="#">Nastech</a>		NDA
Salmon calcitonin	<a href="#">Unigene</a>	Nasal	3
Salmon calcitonin	<a href="#">Unigene</a>	Oral	2
Salmon calcitonin (SMC 021)	<a href="#">Novartis, Emisphere, Nordic</a>	Oral	3
Salmon calcitonin	<a href="#">Nobex (Biocon)</a>	Oral	3
<b>Vitamin D</b>			
ED 71	<a href="#">Bone/ Chugai</a>	Activated Vitamin D derivative	3
Doxercalciferol (Hectorol)	<a href="#">Bone Care Int.</a>	Synthetic Vitamin D	
<b>Nitrates: Research is going on to determine if nitrates can prevent osteoporosis in women.</b>			
Isosorbide mononitrate	<a href="#">St. Michael's Hospital, Toronto</a>		3
Nitroglycerine	<a href="#">Canadian Institutes of Health Research (CIHR)</a>		3
HCT 1026 (NO releasing Derivative of NSAIDs)	<a href="#">NicOx SA</a>		2
<b>Selective Androgen Receptor Modulator (SARM)</b>			
LGD-2941	<a href="#">Ligand, TAP</a>		3
LGD-3303	<a href="#">Ligand, TAP</a>		3
Ostarine	<a href="#">GTx</a>		2
Intermittent Versus Continuous Androgen Suppression	<a href="#">Ontario Cancer Research Network</a>		
Mk 0733	<a href="#">Merck</a>		1
TH0229	Theratechnologies		
c-8500	Merck		2
c-3578	Merck		2

apomorphine	Ilex Oncology		2	
Genistein	<a href="#">Primus Pharmaceuticals, Inc.</a>	isoflavones have been shown to interact with animal and human estrogen receptors, causing effects in the body similar to those caused by the hormone estrogen.	Available	
Soy estrogens	<a href="#">(NIAMS)</a>		3	
Hesperidin	<a href="#">Nestle clinical nutrition</a>		3	
Davallia Divaricata	<a href="#">National Taiwan University Hospital</a>		1	
Atorvastatin	<a href="#">[1]</a>			
Potassium citrate	<a href="#">Weill Medical College of Cornell University</a>		4	
Phosphorus	<a href="#">National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)</a>		3	

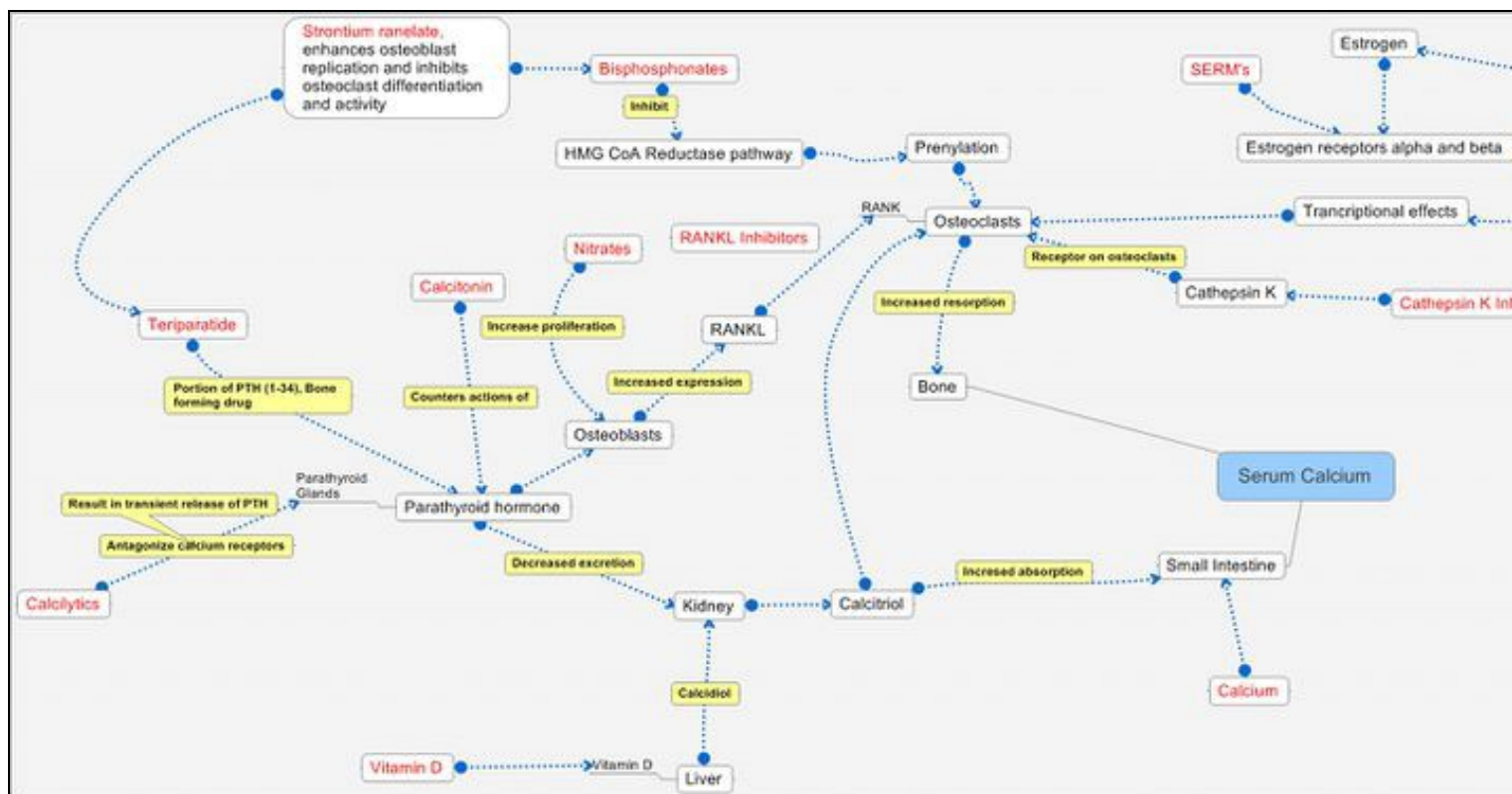
## Devices

Hip Protector	Hip pads with special underwear with pockets		Children's Mercy Hospital Kansas City	
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## Pathways



PRODUCT PATHWAY



## PRODUCT PIPELINE

### Market Information

#### Prescription Trends in USA

Source: Arch Intern Med. 2004;164:1525-1530

	1988	1990	1992	1994	1996	1998	2000	2002	2003
<b>Patients (Millions)</b>	NA	0.6	0.6	0.5	1.2	2	2.6	2.8	3.6
<b>Drugs Prescribed %</b>									
<b>Bisphosphonates (total)</b>	1	9	17	14	48	49	54	71	73
Alendronate	0	0	0	0	45	47	48	53	51
Risedronate	0	0	0	0	0	0	4	17	22
Etidronate	1	9	17	14	3	1	1	0	0
<b>Calcium</b>	39	33	33	43	31	26	29	26	24
<b>Calcitonins</b>	5	9	10	13	13	16	15	7	5
<b>Estrogens</b>	35	25	33	27	17	12	8	5	3
<b>SERMs</b>	0	0	0	0	0	9	14	12	12

### Clinical Trials

Trial No.	Condition	Description	Intervention	Therapy	Route of admn	Sponsors & Collaborators	Phase	Date
1	Postmenopausal Osteoporosis	Investigate Patient Preference On Dosing In Ibandronate And Risedronate in Korean women	Ibandronate	Drug	Oral	GlaxoSmithKline	Phase IV	May-07
2	Osteoporosis Osteopenia	Texture Analysis for Postmenopausal Osteoporosis	Alendronate	Drug	Oral	University of Chicago	-	Mar-07
3	Osteoporosis	A Phase II Study Evaluating	SB-751689	Drug	Oral	GlaxoSmithKline	Phase II	May-07



		SB-751689 in Post-Menopausal Women With Osteoporosis.						
4	Osteoporosis	Fall prevention program	Procedure	-	-	Sint Maartenskliniek ZonMw: The Netherlands Organisation for Health Research and Development		Apr-07
5	Osteoporosis Osteopenia	High Dosage Vitamin D and Osteoporosis	Cholecalciferol	Drug	Oral	University Hospital of North Norway	Phase IV	Jun-07
6	Osteoporosis	Effect of PTH(1-84)or Strontium Ranelate on Bone Formation Measured by Bone Markers	Parathyronine hormone	Drug	Oral	Nycomed	Phase IV	May-07
7	Post-Menopausal Osteoporosis	A Study of Quarterly Intravenous Bonviva (Ibandronate) in Women With Post-Menopausal Osteoporosis.	ibandronate [Bonviva/Boniva]	Drug	Intravenous	Hoffmann-La Roche	Phase IV	Jul-07
8	Osteoporosis	A Study for Patients With Osteoporosis	1.Salmon Calcitonin 2.Teriparatide	Drug	Nose/intravenous	Eli Lilly and Company	Phase III	Jun-07
9	Osteoporosis	Safety/Efficacy of Zoledronic Acid and Alendronate on Bone Metabolism in Post Menopausal Women With Osteoporosis	Zoledronic acid and alendronate	Drug	Oral	Novartis	Phase III	May-07
10	Osteoporosis	Efficacy in Reducing Fractures and Safety of Zoledronic Acid in Men With Osteoporosis	zoledronic acid	Drug	Intravenous	Novartis	Phase III	Feb-07
11	Osteoporosis	Davallia Divaricata BL: The Use of Traditional Chinese Native Medicine for Osteoporosis	Gu-Sui-Bu (Davallia Divaricata)	Drug		National Taiwan University Hospital	Phase I	Jan-07
12	Osteoporosis	Dose Ranging Study - Macroflux PTH in Postmenopausal Women With Osteoporosis	Macroflux PTH	Drug	Subcutaneuos	The Macroflux Corporation	Phase II	Jun-07
13	Osteoporosis	Fosamax for Childhood Cancer Survivors	Alendronate	Drug	Oral	Chinese University of Hong Kong	Phase III	Oct-06
14	Osteoporosis	This study is currently recruiting patients.	Parathyroid Hormone (PTH)	Drug	Subcutaneuos	Nycomed	-	Feb-07
15	Osteoporosis	This study is currently recruiting patients.	Alendronate with cholecalciferol and Os-Cal with extra D	Drug	Oral	National Institute on Aging (NIA),Glaxosmithkline	Phase III	May-07
16	Primary Osteoporosis	Phase II/III Clinical Study of R484iv (Ibandronic Acid) for Primary Osteoporosis	Ibandronic acid	Drug	Oral	Chugai Pharmaceutical	Phase III	Mar-07
17	Postmenopausal Osteoporosis, Back pain and	Effect of Teriparatide Compared to	Teriparatide and risedronate	Drug	Oral/Subcutaneuos	Eli Lilly and Company	Phase III	Jul-07

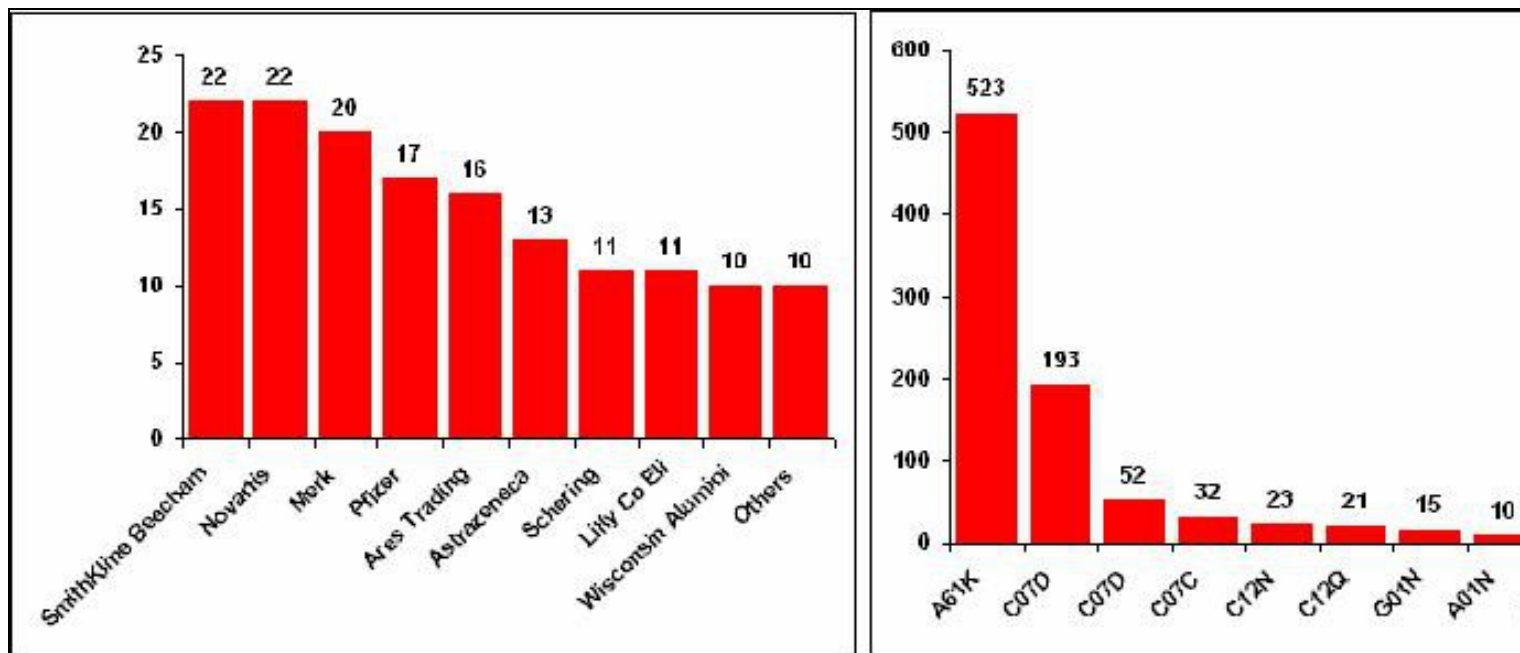
	Spinal Fracture	Risedronate on Back Pain in Women With a Spine Fracture Caused by Osteoporosis						
18	Osteoporosis	BONDIR Study: A Study of Intravenous Bonviva (Ibandronate) After Recent Vertebral Osteoporotic Fracture in Patients With Osteoporosis.	Ibandronate [Bonviva/Boniva]	Drug	Intravenous	Hoffmann-La Roche	Phase III	Jul-07

## Intellectual Property

### Search strategy

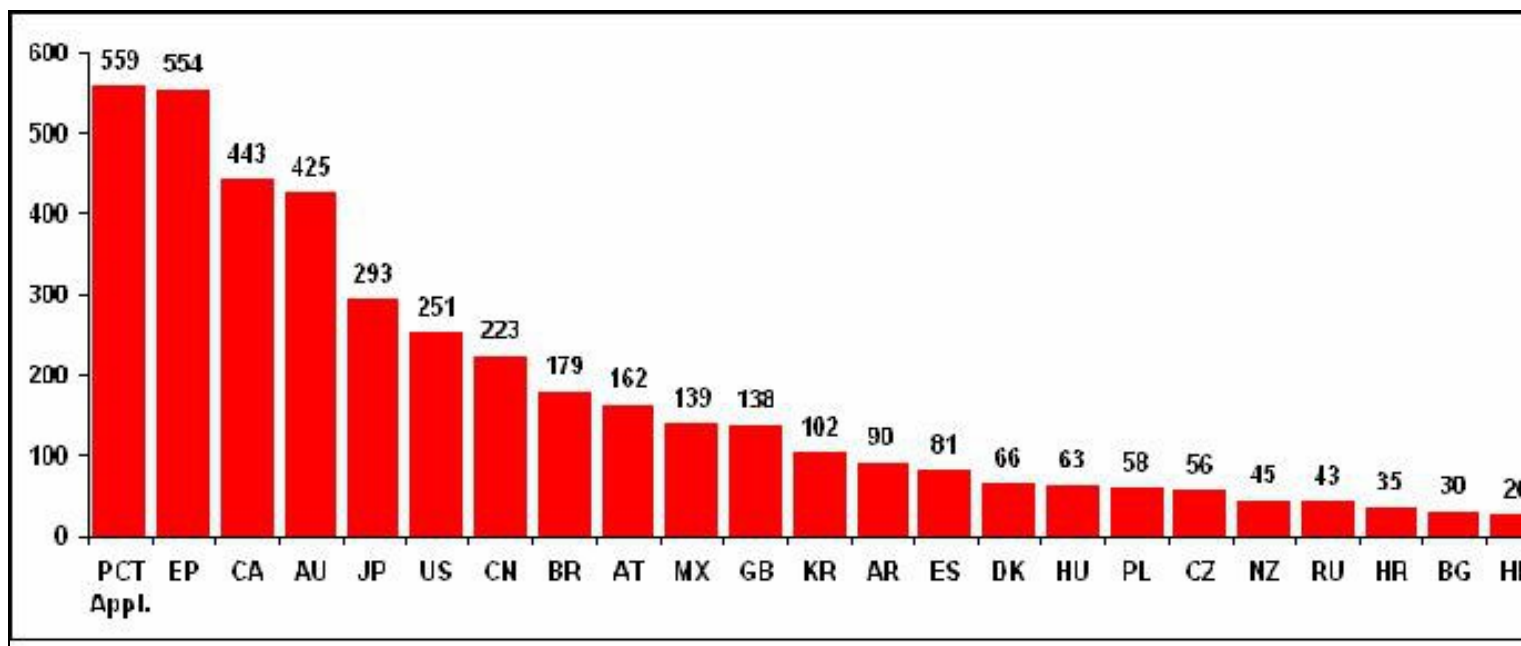
- **Database/Vendor:** Micropat
- **Search scope:** US Granted US Applications EP-A EP-B WO JP (bibliographic data only) DE-C,B DE-A DE-T DE-U GB-A FR-A; **Claims**
- **Years:** Issue/Publication Date: >20051231
- **Search String:** ((Osteoporosis OR (bone Near3 regeneration)) AND (treatment))
- **Hits:** 1261/982 patents (with/with out family members)
- **Date of search:** 14th September 2007

### Top players and IPC classes



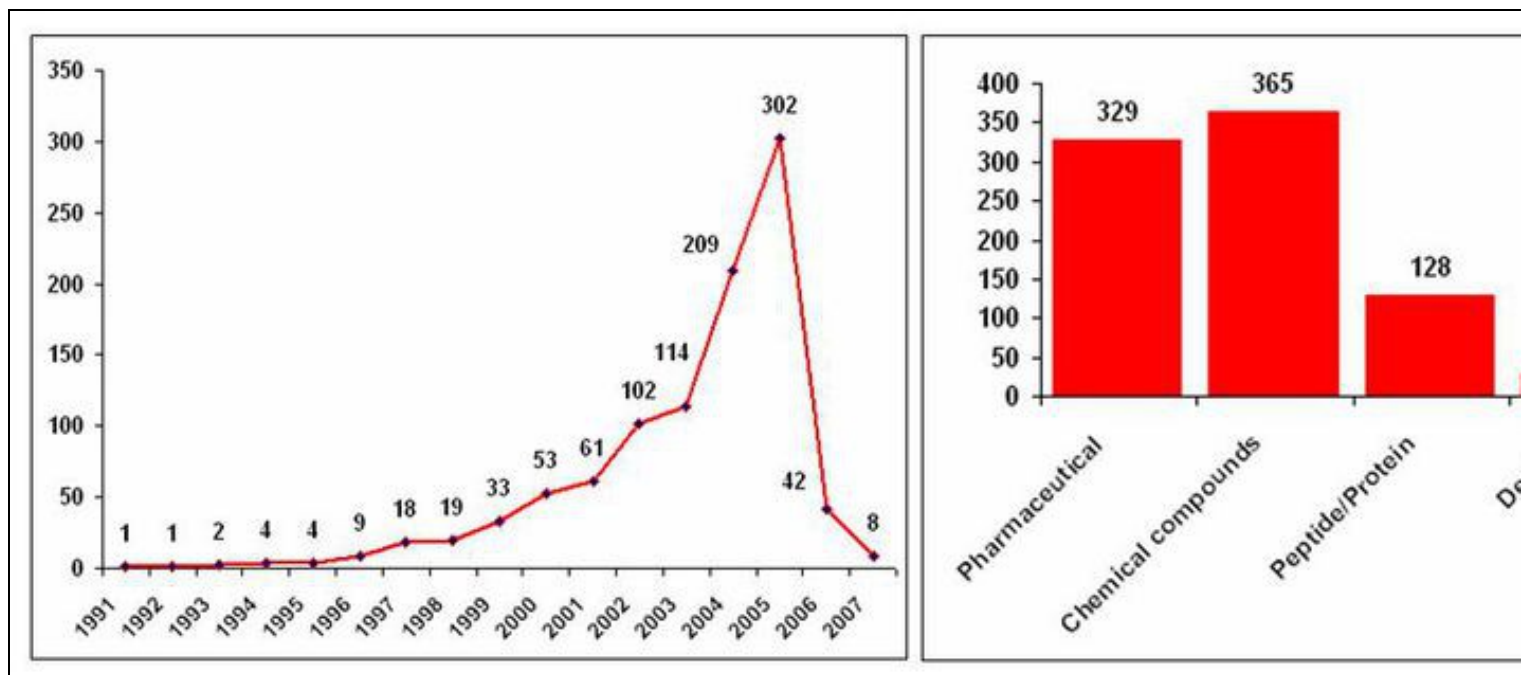
### Geographical Distribution and Treatment Approaches





### IP activity and Treatment Approaches

- Decline in the IP activity during 2006 and 2007 is due 18 months publication delay of patent document.



### Conferences

- International Conference on Osteoporosis and Bone Research to be held on Oct 15-18, 2008 in Beijing, China.
- 2008 IOF World Congress on Osteoporosis to be held on December 2-7, 2008, Bangkok, Thailand
- 2007 World Congress on Osteoarthritis, December 6-9, 2007, Marriott Harbor Beach Resort & Spa in fabulous Ft. Lauderdale, Florida
- American Society of Bone and Mineral Research Annual Meeting, September 12-16, 2008, Montreal, Canada

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## Contact Dolcera

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