

# Older Americans

PRESENTED BY AMERICA'S PHARMACEUTICAL RESEARCH COMPANIES

## More Than 2,000 Medicines in Clinical Testing to Combat Diseases of Aging

The population of Americans over 65 is on the rise, and the pace will only increase in coming years.

Indeed, beginning in just three short years, the first of America's baby-boom generation will begin turning age 65. As life expectancy continues to rise, older Americans face new and growing challenges to their health, productivity and independence—from geriatric conditions to complications from diseases like cancer, cardiovascular disease and diabetes.

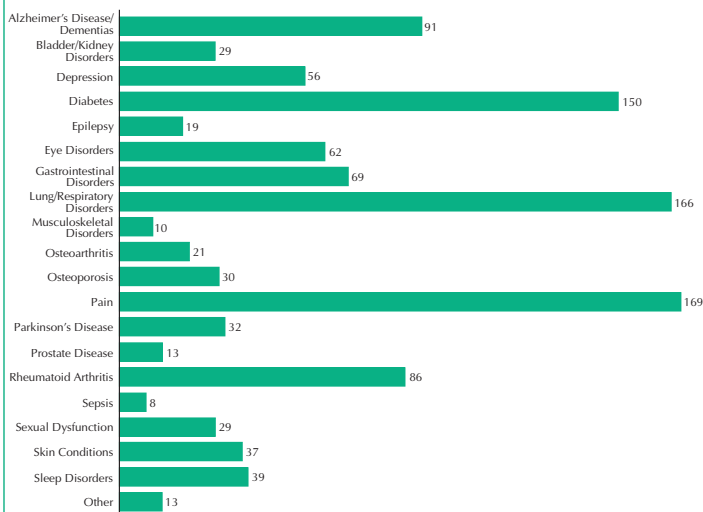
America's pharmaceutical research and biotechnology companies are working to help Americans live longer, healthier and more productive lives. A new report finds that more than 2,000 medicines are in development for diseases of aging, including 277 for heart disease and stroke, 750 for cancer, and 1,026 for such debilitating diseases as Alzheimer's, diabetes, and osteoporosis. Detailed information on medicines in the pipeline for cardiovascular diseases and for cancer may be found at [www.phrma.org](http://www.phrma.org). Medicines in development for diseases of aging in this report include:

- 91 for Alzheimer's disease, which could afflict 16 million people by 2050 unless a cure or prevention is found.
- 56 for depression, which affects an estimated 6.5 million Americans 65 and older.
- 150 for diabetes, which affects 12.2 million Americans age 60 and older.
- 30 for osteoporosis, a major health threat for an estimated 44 million Americans age 50 and older.
- 32 for Parkinson's disease, 60,000 new cases of which are diagnosed each year.

Other medicines in development for older Americans target bladder and kidney diseases, eye disorders, gastrointestinal disorders, osteoarthritis, pain, prostate disease, lung and respiratory disorders, rheumatoid arthritis, skin conditions and other conditions of aging. All of the medicines in this report are either in human clinical trials or await approval by the U.S. Food and Drug Administration. Many of the medicines use cutting-edge knowledge and technology to attack diseases in different ways. These include:

- A medicine that aims to prevent or reverse progression of Alzheimer's disease by using a human monoclonal antibody specifically designed to remove beta amyloid protein from the brain.

### MEDICINES IN DEVELOPMENT FOR OLDER AMERICANS\*



\*Some medicines are listed in more than one category.

- One potential first-in-class medicine being developed addresses the underlying cause of type 2 diabetes by modulating genes responsible for insulin sensitization.
- A potential medicine that activates ion channels in the brain that are important in the regulation of certain nerve cells. In clinical trials, the medicine has shown activity against epileptic seizures.

Important as these medicines in development are, the medicines only work if those in need can get them. Fortunately, the effort to help seniors get the medicines they need at affordable prices has improved with Medicare's guaranteed prescription drug benefit, which was instituted in 2006.

These medicines in development provide new hope to older Americans seeking to live longer, more independent and healthier lives.

Billy Tauzin  
President and CEO  
PhRMA

# Medicines in Development for Older Americans

## ALZHEIMER'S DISEASE/DEMENTIAS

Product Name	Sponsor	Indication	Development Status*
239512 (histamine H3 receptor antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	dementia	Phase I (888) 825-5249
742457 (serotonin 6 receptor antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	Alzheimer's disease	Phase II (888) 825-5249
933776 (mAb)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	Alzheimer's disease	Phase I (888) 825-5249
ABT-089	Abbott Laboratories <i>Abbott Park, IL</i>	Alzheimer's disease	Phase II (847) 937-6100
ABT-107	Abbott Laboratories <i>Abbott Park, IL</i>	cognition disorders	Phase I (847) 937-6100
ABT-560	Abbott Laboratories <i>Abbott Park, IL</i>	cognition disorders, dementia	Phase I (847) 937-6100
AD01	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	Alzheimer's disease	Phase I (888) 825-5249
<b>Agilect®</b> rasagiline mesylate	TEVA Pharmaceuticals USA <i>North Wales, PA</i>	Alzheimer's disease	Phase II (215) 591-3000
AL-108 (intranasal)	Allon Therapeutics <i>Vancouver, BC</i>	Alzheimer's disease, mild cognitive impairment	Phase II (604) 736-0634
AL-208	Allon Therapeutics <i>Vancouver, BC</i>	mild cognitive impairment associated with coronary artery bypass graft surgery	Phase II (604) 736-0634
arundic acid	Ono Pharma USA <i>Lawrenceville, NJ</i>	Alzheimer's disease	Phase II (609) 219-1010
AV1	Avid Radiopharmaceuticals <i>Philadelphia, PA</i> Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	Alzheimer's disease (diagnosis of early-stage disease)	Phase I (215) 966-6208 (888) 842-2937
AV45	Avid Radiopharmaceuticals <i>Philadelphia, PA</i>	Alzheimer's disease (diagnosis of early-stage disease)	Phase II (215) 966-6208
AV965	Avera Pharmaceuticals <i>San Diego, CA</i>	Alzheimer's disease, cognition disorders	Phase I (858) 452-3570

\* For more information about a specific medicine in this report, please call the telephone number listed.

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Product Name	Sponsor	Indication	Development Status
<b>Avandia®</b> rosiglitazone	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	Alzheimer's disease (adjunctive therapy and monotherapy) (see also diabetes, lung)	Phase III (888) 825-5249
AVE8112 (PDE IV inhibitor)	sanofi-aventis <i>Bridgewater, NJ</i>	Alzheimer's disease	Phase I (800) 633-1610
AZD0328	AstraZeneca <i>Wilmington, DE</i>	Alzheimer's disease	Phase I (800) 236-9933
bapineuzumab (AAB-001)	Elan Pharmaceuticals <i>New York, NY</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	Alzheimer's disease (IV-infusion) ----- Alzheimer's disease (subcutaneous)	Phase III (800) 934-5556 ----- Phase II (800) 934-5556
begacestat	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	Alzheimer's disease in elderly patients	Phase I (800) 934-5556
C105	Sention <i>Providence, RI</i>	mild cognitive impairment	Phase II (401) 272-7177
CAD106	Cytos Biotechnology <i>Zurich, Switzerland</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	Alzheimer's disease	Phase II (888) 669-6682
CERE-110	Ceregene <i>San Diego, CA</i>	Alzheimer's disease	Phase I (858) 458-8800
<b>Corlux™</b> mifepristone	Corcept Therapeutics <i>Menlo Park, CA</i>	Alzheimer's disease (see also depression)	Phase II (650) 327-3270
CTS-21166	Astellas Pharma US <i>Deerfield, IL</i> CoMentis <i>South San Francisco, CA</i>	Alzheimer's disease	Phase I (800) 727-7003 (650) 869-7600
CX717	Cortex Pharmaceuticals <i>Irvine, CA</i>	Alzheimer's disease (see also sleep)	Phase II (949) 727-3157
CX1739	Cortex Pharmaceuticals <i>Irvine, CA</i>	Alzheimer's disease	Phase I (949) 727-3157
DAR-100	DarPharma <i>Chapel Hill, NC</i>	cognition disorders (see also Parkinson's)	Phase II (919) 403-4348
DEBIO-9902 (new tablet formulation)	Debiovision <i>Montreal, QC</i>	Alzheimer's disease in elderly patients	Phase I (514) 842-9976
<b>Dimebon™</b> dimebolin	Medivation <i>San Francisco, CA</i> Pfizer <i>New York, NY</i>	Alzheimer's disease ----- Alzheimer's disease (combination therapy)	Phase III (415) 543-3470 (860) 732-5156 ----- Phase I (415) 543-3470 (860) 732-5156
docosahexaenoic acid	Martek Biosciences <i>Columbia, MD</i>	Alzheimer's disease	Phase III (410) 740-0081

## ALZHEIMER'S DISEASE/DEMENTIAS

Product Name	Sponsor	Indication	Development Status
E2012	Eisai Medical Research <i>Ridgefield Park, NJ</i>	Alzheimer's disease	Phase I (888) 422-4743
EGb-761	Ipsen <i>Milford, MA</i>	Alzheimer's disease	Phase III (508) 478-8900
ELND-005/ AZD-103	Elan Pharmaceuticals <i>New York, NY</i> Transition Therapeutics <i>Toronto, QC</i>	Alzheimer's disease	Phase II (800) 252-3526 (416) 260-7770
ELND-006	Elan Pharmaceuticals <i>New York, NY</i>	Alzheimer's disease	Phase I (800) 252-3526
EVP6124	EnVivo Pharmaceuticals <i>Watertown, MA</i>	Alzheimer's disease	Phase I (617) 225-4250
<b>Exebryl-1®</b>	ProteoTech <i>Kirkland, WA</i>	Alzheimer's disease	Phase I (425) 823-0400
<b>Exelon®</b> rivastigmine	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	vascular dementia	Phase III (888) 669-6682
<b>Gammagard Liquid™</b> immune globulin	Baxter International <i>Deerfield, IL</i>	Alzheimer's disease	Phase II (800) 422-9837
gamma secretase inhibitor	Bristol-Myers Squibb <i>Princeton, NJ</i>	Alzheimer's disease	in clinical trials (212) 546-4000
GSI-136	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	Alzheimer's disease	Phase I (800) 934-5556
HT-0712	Helicon Therapeutics <i>San Diego, CA</i>	cognition disorders	Phase I (858) 246-8120
huperzine A	Neuro-Hitech <i>New York, NY</i>	Alzheimer's disease	Phase II (212) 594-1225
ispronicline (AZD3480)	AstraZeneca <i>Wilmington, DE</i> Targacept <i>Winston-Salem, NC</i>	cognition disorders	Phase II (800) 236-9933 (336) 480-2100
<b>Ketasyn™</b> (AC-1202)	Accera <i>Broomfield, CO</i>	Alzheimer's disease, age-associated memory impairment	Phase II (303) 999-3700
L-830982	Merck <i>Whitehouse Station, NJ</i>	cognition disorders	Phase II (800) 672-6372
leuprorelin (VP-4896)	Voyager Pharmaceuticals <i>Raleigh, NC</i>	Alzheimer's disease	Phase III (919) 846-4880
<b>Lipitor®</b> atorvastatin	Pfizer <i>New York, NY</i>	Alzheimer's disease (combination therapy)	Phase III (860) 732-5156
LX-6171	Lexicon Pharmaceuticals <i>The Woodlands, TX</i>	cognition disorders	Phase II (281) 863-3000
LY-450139 (semagacestat)	Eli Lilly <i>Indianapolis, IN</i>	Alzheimer's disease	Phase III (800) 545-5979

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Product Name	Sponsor	Indication	Development Status
LY-451395	Eli Lilly <i>Indianapolis, IN</i>	Alzheimer's disease	Phase II (800) 545-5979
LY-2062430	Eli Lilly <i>Indianapolis, IN</i>	Alzheimer's disease	Phase II (800) 545-5979
MABT 5102A	Genentech <i>South San Francisco, CA</i>	Alzheimer's disease	Phase I (800) 626-3553
<b>Marinol®</b> dronabinol	Unimed Pharmaceuticals <i>Marietta, GA</i>	dementia	Phase II completed (770) 578-9000
MEM 1003	Memory Pharmaceuticals <i>Montvale, NJ</i>	Alzheimer's disease	Phase II (201) 802-7100
		mild cognitive impairment, vascular dementia	Phase I (201) 802-7100
MEM 1414	Memory Pharmaceuticals <i>Montvale, NJ</i>	Alzheimer's disease, mild cognitive impairment	Phase I (201) 802-7100
MEM 3454	Memory Pharmaceuticals <i>Montvale, NJ</i> Roche <i>Nutley, NJ</i>	Alzheimer's disease	Phase II completed (201) 802-7100 (973) 235-5000
MEM 63908 (R4996)	Memory Pharmaceuticals <i>Montvale, NJ</i> Roche <i>Nutley, NJ</i>	Alzheimer's disease	Phase I (201) 802-7100 (973) 235-5000
memantine ER (once-daily, extended-release)	Forest Laboratories <i>New York, NY</i>	Alzheimer's disease	Phase III (800) 947-5227
<b>Memryte™</b> leuprolide acetate implant	DURECT <i>Cupertino, CA</i> Voyager Pharmaceutical <i>Raleigh, NC</i>	Alzheimer's disease	Phase III (408) 777-1417 (919) 846-4880
midazolam intranasal	Intranasal Therapeutics <i>Saddle Brook, NJ</i>	mild cognitive impairment	Phase I (201) 843-3308
MK-0249	Merck <i>Whitehouse Station, NJ</i>	Alzheimer's disease	Phase II (800) 672-6372
<b>Motiva™</b> nefiritam	Neuren Pharmaceuticals <i>Bethesda, MD</i>	cognition disorders, dementia (see also depression)	Phase II (301) 941-1830
neramexane	Forest Laboratories <i>New York, NY</i>	Alzheimer's disease	Phase III (800) 947-5227
NGX267	TorreyPines Therapeutics <i>La Jolla, CA</i>	Alzheimer's disease	Phase I (858) 623-5665
NIC5-15	Humanetics <i>Eden Prairie, MN</i>	Alzheimer's disease	Phase II (952) 937-7660
nicergoline	Pfizer <i>New York, NY</i>	Alzheimer's disease	Phase III (860) 732-5156
N-PEP-12	Ebewe Pharma <i>Unterach, Austria</i>	cognition disorders	Phase I www.ebewe.com

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Product Name	Sponsor	Indication	Development Status
<b>Oxigon™</b> indolepropionic acid derivative	Intellect Neurosciences New York, NY	Alzheimer's disease	Phase I (212) 448-9300
PAZ-417	Wyeth Pharmaceuticals Collegeville, PA	Alzheimer's disease	Phase I (800) 934-5566
PF-3654746	Pfizer New York, NY	cognition disorders in Alzheimer's disease	Phase I (860) 732-5156
PF-4360365	Pfizer New York, NY	Alzheimer's disease	Phase I (860) 732-5156
PF-4447943	Pfizer New York, NY	cognition disorders in elderly patients	Phase I (860) 732-5156
PF-4494700	Pfizer New York, NY	Alzheimer's disease	Phase II (860) 732-5156
PRX-03140	EPIX Pharmaceuticals Lexington, MA GlaxoSmithKline Rsch. Triangle Park, NC	Alzheimer's disease	Phase II (781) 372-3260 (888) 825-5249
PRX-07034	EPIX Pharmaceuticals Lexington, MA	Alzheimer's disease, cognition disorders	Phase I (781) 372-3260
R1450	Roche Nutley, NJ	Alzheimer's disease	Phase I (973) 235-5000
R1500	Roche Nutley, NJ	Alzheimer's disease	Phase I (973) 235-5000
R1577	Roche Nutley, NJ	Alzheimer's disease	Phase I (973) 235-5000
<b>Razadyne®</b> galantamine	Johnson & Johnson Pharmaceutical Research & Development Raritan, NJ	mild cognitive impairment, vascular dementia	Phase III (800) 817-5286
safinamide	EMD Serono Rockland, MA	Alzheimer's disease (see also Parkinson's, sleep)	Phase I (800) 283-8088
SAM-315	Wyeth Pharmaceuticals Collegeville, PA	Alzheimer's disease	Phase I (800) 934-5556
SAM-531	Wyeth Pharmaceuticals Collegeville, PA	Alzheimer's disease	Phase II (800) 934-5556
SGS 518	Saegis Pharmaceuticals Half Moon Bay, CA	mild cognitive impairment	Phase II (650) 560-0210
SGS 742	Saegis Pharmaceuticals Half Moon Bay, CA	Alzheimer's disease, mild cognitive impairment	Phase II (650) 560-0210
solanezumab	Eli Lilly Indianapolis, IN	Alzheimer's disease	Phase II (800) 565-5979
SRA-444	Wyeth Pharmaceuticals Collegeville, PA	Alzheimer's disease	Phase I (800) 934-5556
SSR180711 ( $\alpha 7$ nicotinic partial agonist)	sanofi-aventis Bridgewater, NJ	Alzheimer's disease	Phase I (800) 633-1610

## ALZHEIMER'S DISEASE/DEMENTIAS

Product Name	Sponsor	Indication	Development Status
SYN-114	Roche Nutley, NJ Synosia Therapeutics South San Francisco, CA	cognition disorders	Phase I (973) 235-5000 (650) 244-4850
T-817MA	Toyama Chemical Tokyo, Japan	Alzheimer's disease	Phase II
TC-5619	AstraZeneca Wilmington, DE Targacept Winston-Salem, NC	cognition disorders	Phase I (800) 236-9933 (336) 480-2100
V950	Merck Whitehouse Station, NJ	Alzheimer's disease	Phase I (800) 672-6372

## BLADDER/KIDNEY DISORDERS

Product Name	Sponsor	Indication	Development Status
AA-4010	Auxilium Pharmaceuticals Malvern, PA	overactive bladder	Phase I (484) 321-5900
<b>Anturol®</b> oxybutynin transdermal gel	Antares Pharma Ewing, NJ	overactive bladder	Phase III (609) 359-3020
<b>Botox®</b> botulinum toxin A	Allergan Irvine, CA	overactive bladder (see also prostate)	Phase II (800) 433-8871
casopitant	GlaxoSmithKline Rsch. Triangle Park, NC	overactive bladder (see also depression)	Phase II (888) 825-5249
DDP200	Dynogen Pharmaceuticals Waltham, MA	overactive bladder	Phase II (781) 839-5100
DDP225	Dynogen Pharmaceuticals Waltham, MA	overactive bladder (see also gastrointestinal)	Phase I (781) 839-5100
fesoterodine	Pfizer New York, NY	overactive bladder	application submitted (860) 732-5156
FP1097	FemmePharma Wayne, PA	urinary incontinence	Phase II (610) 995-0801
GRC-6211	Eli Lilly Indianapolis, IN	urinary incontinence (see also pain)	Phase I (800) 545-5979
hMaxi-K gene therapy	Ion Channel Innovations New York, NY	overactive bladder (see also sexual dysfunction)	Phase I (212) 639-1561
MK-0594	Merck Whitehouse Station, NJ	overactive bladder	Phase II (800) 672-6372
MK-0634	Merck Whitehouse Station, NJ	overactive bladder, urinary incontinence	Phase II (800) 672-6372
MN-246	MediciNova San Diego, CA	urinary incontinence	Phase I (858) 373-1500
oxybutynin controlled-release	Penwest Pharmaceuticals Danbury, CT	urinary incontinence	in clinical trials (203) 796-3700

## BLADDER/KIDNEY DISORDERS

Product Name	Sponsor	Indication	Development Status
<b>Oxytrol®</b> oxybutynin transdermal gel	Watson Pharmaceuticals Corona, CA	overactive bladder	application submitted (800) 249-5499
PF-184298	Pfizer New York, NY	stress incontinence	Phase I completed (860) 732-5156
R1646	Roche Nutley, NJ	overactive bladder (see also pain)	Phase I (973) 235-5000
SMP-986	Dainippon Sumitomo Pharma Osaka, Japan	overactive bladder	Phase II
solabegron	GlaxoSmithKline Rsch. Triangle Park, NC	overactive bladder (new delivery system) (see also gastrointestinal)	Phase I (888) 825-5249
solifenacin/ tamsulosin combination	Astellas Pharma US Deerfield, IL	bladder dysfunction in men (see also prostate)	Phase II (800) 727-7003
SSR240600 (NK1 antagonist)	sanofi-aventis Bridgewater, NJ	overactive bladder, urinary incontinence	Phase II (800) 633-1610
SVT-40776	SALVAT USA Coral Gables, FL	overactive bladder	Phase II (305) 774-9727
TAK-363	Takeda Pharmaceuticals North America Deerfield, IL	urinary frequency, urinary incontinence	Phase I (224) 554-6500
TRPV1 antagonist	Pfizer New York, NY	urinary incontinence (see also pain)	Phase I (860) 732-5156
UK-369003	Pfizer New York, NY	overactive bladder (see also prostate)	Phase II (860) 732-5156
URG301	Urigen Pharmaceuticals Burlingame, CA	overactive bladder (see also pain)	Phase I (650) 259-0239
vardenafil	Bayer HealthCare Pharmaceuticals Wayne, NJ	overactive bladder	Phase I (888) 842-2937
<b>Vestra®</b> reboxetine	Pfizer New York, NY	urinary incontinence (see also depression)	Phase II (860) 732-5156
YM-178	Astellas Pharma US Deerfield, IL	overactive bladder	Phase III (800) 727-7003
		urination disorders in men	Phase II (800) 727-7003

## DEPRESSION

Product Name	Sponsor	Indication	Development Status
163090 (serotonin receptor antagonist)	GlaxoSmithKline Rsch. Triangle Park, NC	depression	Phase I (888) 825-5249

## DEPRESSION

Product Name	Sponsor	Indication	Development Status
372475 (triple monoamine reuptake inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	depression	Phase II (888) 825-5249
424887 (dual neurokinin receptor 1 antagonist and selective serotonin reuptake inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	depression	Phase I (888) 825-5249
561679 (CRF receptor 1 antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Neurocrine Biosciences <i>San Diego, CA</i>	depression (see also gastrointestinal)	Phase I (888) 825-5249 (858) 617-7600
586529 (CRF receptor 1 antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Neurocrine Biosciences <i>San Diego, CA</i>	depression	Phase I (888) 825-5249 (858) 617-7600
588045 (serotonin 1 receptor antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	depression	Phase I (888) 825-5249
856553 (p38 MAP kinase inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	depression (see also lung, rheumatoid arthritis)	Phase II (888) 825-5249
876008 (CRF receptor 1 antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Neurocrine Biosciences <i>San Diego, CA</i>	depression (see also gastrointestinal)	Phase II (888) 825-5249 (858) 617-7600
adatanserin	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	depression	Phase II (800) 934-5556
AZD2327	AstraZeneca <i>Wilmington, DE</i>	depression	Phase I (800) 236-9933
AZD6765	AstraZeneca <i>Wilmington, DE</i>	depression	Phase I/II (800) 236-9933
casopitant	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	depression (see also bladder)	Phase II (888) 825-5249
<b>Corlux™</b> mifepristone	Corcept Therapeutics <i>Menlo Park, CA</i>	depression (see also Alzheimer's)	Phase III (650) 327-3270
DOV-21947	DOV Pharmaceutical <i>Somerset, NJ</i>	depression	Phase II (732) 907-3600
E2508	Eisai Medical Research <i>Ridgefield Park, NJ</i>	depression	Phase I (888) 422-4743
<b>Geodon®</b> ziprasidone	Pfizer <i>New York, NY</i>	bipolar depression	Phase III (860) 732-5156

## DEPRESSION

Product Name	Sponsor	Indication	Development Status
gepirone ER (extended-release)	Fabre Kramer Pharmaceuticals <i>Houston, TX</i> GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	depression	application submitted (713) 975-6900 (888) 825-5249
<b>Lamictal</b> <sup>®</sup> lamotrigine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	depression (see also pain)	in clinical trials (888) 825-5249
LU AA 21004	Lundbeck Research USA <i>Paramus, NJ</i> Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	depression	Phase III (224) 554-6500
LU AA 24530	Lundbeck Research USA <i>Paramus, NJ</i> Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	depression	Phase II (224) 554-5400
<b>Motiva</b> <sup>®</sup> nefiracetam	Neuren Pharmaceuticals <i>Bethesda, MD</i>	depression (see also Alzheimer's)	Phase II (301) 941-1831
<b>Nectiv</b> <sup>™</sup> traxoprodil	Pfizer <i>New York, NY</i>	co-administration with paroxetine for treatment-resistant depression (see also Parkinson's)	Phase II (860) 732-5156
nemifitide	Tetragenex Pharmaceuticals <i>Park Ridge, NJ</i>	depression	Phase II (201) 505-1300
NSD-788	NeuroSearch <i>Ballerup, Denmark</i> GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	depression	Phase I (888) 825-5249
<b>Nuvigil</b> <sup>™</sup> armodafinil	Cephalon <i>Frazer, PA</i>	bipolar depression	Phase II (610) 344-0200
ONO 2333Ms	ONO Pharma USA <i>Hackensack, NJ</i>	depression	Phase II (201) 342-8228
ORG-26576	Schering-Plough <i>Kenilworth, NJ</i>	depression	Phase I/II (908) 298-4000
ORG-34517	Schering-Plough <i>Kenilworth, NJ</i>	depression	Phase II (908) 298-4000
orvepitant	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	depression	Phase I (888) 825-5249
pardoprunox (SLV308)	Solvay Pharmaceuticals <i>Marietta, GA</i>	depression (see also Parkinson's)	Phase II (770) 578-9000
R1647	Roche <i>Nutley, NJ</i>	depression	Phase I (973) 235-5000
<b>Risperdal</b> <sup>®</sup> risperidone	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	depression	Phase III (800) 817-5286

## DEPRESSION

Product Name	Sponsor	Indication	Development Status
SAR102779 (NK2 antagonist)	sanofi-aventis <i>Bridgewater, NJ</i>	depression (see also gastrointestinal)	Phase I (800) 633-1610
saredutant (NK2 antagonist)	sanofi-aventis <i>Bridgewater, NJ</i>	depression	Phase III (800) 633-1610
SEP-225289	Sepracor <i>Marlborough, MA</i>	depression	Phase II (508) 481-6700
SEP-227162	Sepracor <i>Marlborough, MA</i>	depression	Phase I completed (508) 481-6700
SEP-228425	Sepracor <i>Marlborough, MA</i>	depression (see also pain)	Phase I (508) 481-6700
SEP-228432	Sepracor <i>Marlborough, MA</i>	depression	Phase I (508) 481-6700
<b>Serdaxin™</b>	Rexahn Pharmaceuticals <i>Rockville, MD</i>	depression	Phase II (240) 268-5300
<b>Seroquel XR™</b> quetiapine	AstraZeneca <i>Wilmington, DE</i>	depression (adjunctive treatment, monotherapy, prevention of relapse)	application submitted (800) 236-9933
SSR125543 (CRF1 antagonist)	sanofi-aventis <i>Bridgewater, NJ</i>	depression	Phase I (800) 633-1610
SSR149415 (V1B antagonist)	sanofi-aventis <i>Bridgewater, NJ</i>	depression	Phase II (800) 633-1610
SSR411298 (FAAH inhibitor)	sanofi-aventis <i>Bridgewater, NJ</i>	depression	Phase I (800) 633-1610
<b>Symbyax®</b> olanzapine/ fluoxetine combination	Eli Lilly <i>Indianapolis, IN</i>	depression	application submitted (800) 545-5979
TC-5214	Targacept <i>Winston-Salem, NC</i>	depression	Phase II (336) 480-2100
trazodone controlled-release	Labopharm <i>Laval, QC</i>	depression	application submitted (888) 686-1017
triple reuptake inhibitor	Bristol-Myers Squibb <i>Princeton, NJ</i>	depression	in clinical trials (212) 546-4000
TS-041	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> Taisho Pharmaceutical R&D <i>Morristown, NJ</i>	depression	Phase I (800) 817-5286
<b>Tyrima™</b> (CX157)	CeNeRx BioPharma <i>Rsch. Triangle Park, NC</i>	depression	Phase II (919) 234-4650
<b>Valdoxan®</b> agomelatine	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	depression, prevention of depression relapse	Phase III (888) 669-6682
venlafaxine deuterium- substituted	Auspex Pharmaceuticals <i>Vista, CA</i>	depression	Phase I (760) 599-1800

## DEPRESSION

Product Name	Sponsor	Indication	Development Status
Vestra® reboxetine	Pfizer New York, NY	depression (see also bladder)	application submitted (860) 732-5156
vilazodone	Clinical Data Newton, MA	depression	Phase III (617) 527-9933
VPI 013	Otsuka America Pharmaceutical Rockville, MD Pharmos Iselin, NJ	depression	Phase II (732) 452-9556
YKP10A	Johnson & Johnson Pharmaceutical Research & Development Raritan, NJ SK Drug Development Center Fairfield, NJ	depression	Phase II (800) 817-5286 (973) 227-3939
YKP581	Johnson & Johnson Pharmaceutical Research & Development Raritan, NJ SK Drug Development Center Fairfield, NJ	depression	Phase I (800) 817-5286 (973) 227-3939

## DIABETES, TYPE 1 AND TYPE 2

Product Name	Sponsor	Indication	Development Status
11βHSD	Bristol-Myers Squibb Princeton, NJ	diabetes	in clinical trials (212) 546-4000
376501 (PPAR gamma agonist)	GlaxoSmithKline Rsch. Triangle Park, NC	type 2 diabetes	Phase I (888) 825-5249
625019 (PPAR agonist)	GlaxoSmithKline Rsch. Triangle Park, NC	type 2 diabetes	Phase I (888) 825-5249
716155 (albiglutide)	GlaxoSmithKline Rsch. Triangle Park, NC	type 2 diabetes	Phase II (888) 825-5249
756050	GlaxoSmithKline Rsch. Triangle Park, NC	type 2 diabetes	Phase I (888) 825-5249
ABT-279	Abbott Laboratories Abbott Park, IL	type 2 diabetes	Phase I (847) 937-6100
Acomplia® rimonabant	sanofi-aventis Bridgewater, NJ	type 2 diabetes	Phase III (800) 633-1610
AI-401	Autolmmune Pasadena, CA	type 1 diabetes (prevention)	Phase III (626) 792-1235
AKP-020	Akesis Pharmaceuticals La Jolla, CA	type 2 diabetes	Phase II (858) 454-4311

## DIABETES, TYPE 1 AND TYPE 2

Product Name	Sponsor	Indication	Development Status
AKP-111	Akesis Pharmaceuticals <i>La Jolla, CA</i>	type 2 diabetes	Phase I (858) 454-4311
AKP-320	Akesis Pharmaceuticals <i>La Jolla, CA</i>	type 2 diabetes	in clinical trials (858) 454-4311
<b>Albulin™</b> albumin/insulin	Teva Pharmaceuticals USA <i>North Wales, PA</i>	type 1 diabetes, type 2 diabetes	Phase I (215) 591-3000
alogliptin	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	type 2 diabetes	application submitted (224) 554-0000
alogliptin/ pioglitazone	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	type 2 diabetes	application submitted (224) 554-0000
<b>Altace®</b> ramipril	King Pharmaceuticals <i>Bristol, TN</i>	type 2 diabetes (prevention)	Phase III (800) 776-3637
<b>Alveair™</b> inhaled insulin	Coremed <i>Lake Bluff, IL</i>	diabetes	Phase I (847) 549-9098
AMG 108	Amgen <i>Thousand Oaks, CA</i>	diabetes (see also rheumatoid arthritis)	Phase II (800) 772-6436
AMG 221	Amgen <i>Thousand Oaks, CA</i>	type 2 diabetes	Phase I (800) 772-6436
AMG 222	Amgen <i>Thousand Oaks, CA</i>	type 2 diabetes	Phase II (800) 772-6436
AMG 477	Amgen <i>Thousand Oaks, CA</i>	type 2 diabetes	Phase I (800) 772-6436
<b>Apidra® SoloStar®</b> insulin glulisine disposable injection pen	sanofi-aventis <i>Bridgewater, NJ</i>	type 1 diabetes, type 2 diabetes	application submitted (800) 633-1610
ARI-2243	Arisaph Pharmaceuticals <i>Boston, MA</i>	type 2 diabetes	Phase I (617) 292-3322
AT1391 (daily insulin skin patch)	Altea Therapeutics <i>Tucker, GA</i>	type 1 diabetes ----- type 2 diabetes	Phase I/II (678) 495-3100 ----- Phase I (678) 495-3100
ATL-844	PGxHealth <i>New Haven, CT</i>	type 2 diabetes (see also lung)	Phase II (877) 274-9432
autoimmune diabetes vaccine	Diamyd Medical <i>Pittsburgh, PA</i>	type 1 diabetes	Phase III (412) 770-1310
<b>Avandamet® XR</b> rosiglitazone/ metformin extended-release	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	type 2 diabetes	Phase III (888) 825-5249
<b>Avandia®</b> rosiglitazone	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	type 2 diabetes (prevention) (see also Alzheimer's, lung)	Phase III (888) 825-5249

## DIABETES, TYPE 1 AND TYPE 2

Product Name	Sponsor	Indication	Development Status
AVE0010 (GLP1 agonist)	sanofi-aventis <i>Bridgewater, NJ</i>	type 2 diabetes	Phase II (800) 633-1610
AVE0010 (prolonged-release)	sanofi-aventis <i>Bridgewater, NJ</i>	type 2 diabetes	Phase I (800) 633-1610
AVE0897 (balanced PPAR agonist)	sanofi-aventis <i>Bridgewater, NJ</i>	type 2 diabetes	Phase I (800) 633-1610
AVE1625 (CB1 antagonist)	sanofi-aventis <i>Bridgewater, NJ</i>	type 2 diabetes	Phase II (800) 633-1610
AVE2268 (SGLT2 inhibitor)	sanofi-aventis <i>Bridgewater, NJ</i>	type 2 diabetes	Phase II (800) 633-1610
AVR 118	Advanced Viral Research <i>Yonkers, NY</i>	type 2 diabetes	Phase I completed (914) 376-7383
AZD1175	AstraZeneca <i>Wilmington, DE</i>	type 2 diabetes	Phase I (800) 236-9933
AZD2207	AstraZeneca <i>Wilmington, DE</i>	type 2 diabetes	Phase II (800) 236-9933
AZD6370	AstraZeneca <i>Wilmington, DE</i>	type 2 diabetes	Phase I (800) 236-9933
balaglitazone	Dr. Reddy's Laboratories <i>Charlotte, NC</i>	type 2 diabetes	Phase III (866) 733-3952
BAY 73-7977	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	diabetes	Phase I (888) 842-2937
BHT-3021	Bayhill Therapeutics <i>Palo Alto, CA</i>	type 1 diabetes	Phase I/II (650) 320-2800
BI-1356	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	type 2 diabetes	Phase III (800) 243-0127
BI-10773	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	type 2 diabetes	Phase I (800) 243-0127
BI-44847	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	type 2 diabetes	Phase II (800) 243-0127
bromocriptine	S2 Therapeutics <i>Bristol, TN</i> VeroScience <i>Tiverton, RI</i>	type 2 diabetes	Phase III (401) 816-0525
<b>Byetta</b> <sup>®</sup> execatide	Amylin Pharmaceuticals <i>San Diego, CA</i> Eli Lilly <i>Indianapolis, IN</i>	type 2 diabetes (monotherapy)	application submitted (858) 552-2200 (800) 545-5979
canakinumab	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	type 2 diabetes (see also eye, lung, rheumatoid arthritis)	Phase II/III (888) 669-6682

## DIABETES, TYPE 1 AND TYPE 2

Product Name	Sponsor	Indication	Development Status
CCR2 antagonist	Bristol-Myers Squibb <i>Princeton, NJ</i>	diabetes	in clinical trials (212) 235-5000
CE-326597	Pfizer <i>New York, NY</i>	type 2 diabetes	Phase II (860) 732-5156
cetilistat	Alizyme <i>Cambridge, United Kingdom</i>	type 2 diabetes	Phase II www.alizyme.com
CRx-401	CombinatoRx <i>Cambridge, MA</i>	type 2 diabetes	Phase II (617) 301-7000
CVT-3619	CV Therapeutics <i>Palo Alto, CA</i>	diabetes	Phase I (650) 384-8500
dapagliflozin (SGLT2 inhibitor)	AstraZeneca <i>Wilmington, DE</i> Bristol-Myers Squibb <i>Princeton, NJ</i>	diabetes	Phase III (800) 236-9933 (212) 546-4000
dapagliflozin/ metformin combination therapy	AstraZeneca <i>Wilmington, DE</i>	type 2 diabetes	Phase III (800) 236-9933
DiaPep277	Andromeda Biotech <i>Ness Ziona, Israel</i>	latent autoimmune diabetes	Phase II
DIO-902	DiObex <i>San Francisco, CA</i>	type 2 diabetes	Phase II (415) 551-0400
DPP4 inhibitor	Bristol-Myers Squibb <i>Princeton, NJ</i>	diabetes	in clinical trials (212) 546-4000
exenatide intranasal	Amylin Pharmaceuticals <i>San Diego, CA</i> MDRNA <i>Bothell, WA</i>	type 2 diabetes	Phase I completed (858) 552-2200 (425) 908-3600
exenatide LAR (long-acting release)	Alkermes <i>Cambridge, MA</i> Amylin Pharmaceuticals <i>San Diego, CA</i> Eli Lilly <i>Indianapolis, IN</i>	type 2 diabetes	Phase III (858) 552-2200 (800) 545-5979
<b>Galvus</b> <sup>®</sup> vildagliptin	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	type 2 diabetes	application submitted (888) 669-6682
<b>Glinsuna</b> <sup>™</sup> mitiglinide	Elixir Pharmaceuticals <i>Cambridge, MA</i>	type 2 diabetes	Phase III (617) 995-7000
glucokinase activator	Bristol-Myers Squibb <i>Princeton, NJ</i>	diabetes	in clinical trials (212) 546-4000
HDV insulin	Diasome Pharmaceuticals <i>Conshohocken, PA</i>	type 2 diabetes	Phase II (609) 923-9443
HE-3286	Hollis-Eden Pharmaceuticals <i>San Diego, CA</i>	type 2 diabetes (see also gastrointestinal, rheumatoid arthritis)	Phase II (858) 587-9333

## DIABETES, TYPE 1 AND TYPE 2

Product Name	Sponsor	Indication	Development Status
INCB-13739	Incyte <i>Wilmington, DE</i>	type 2 diabetes	Phase II (302) 498-6700
INCB-19602	Incyte <i>Wilmington, DE</i>	type 2 diabetes	Phase II (302) 498-6700
INCB-20817	Incyte <i>Wilmington, DE</i>	type 2 diabetes	Phase II (302) 498-6700
INGAP peptide	Kinexum Metabolics <i>Harper's Ferry, WV</i>	type 1 diabetes	Phase II completed (304) 535-3037
insulin inhalation	Baxter Healthcare <i>Deerfield, IL</i>	diabetes	Phase I (800) 422-9837
insulin inhalation	MicroDose Technologies <i>Monmouth Junction, NJ</i>	diabetes	Phase I completed (732) 355-2100
insulin nasal spray	MDRNA <i>Bothell, WA</i>	type 2 diabetes	Phase II (425) 908-3601
insulin oral	Generex Biotechnology <i>Toronto, ON</i>	type 1 diabetes	Phase III (416) 364-2551
insulin transdermal	Dermisonics <i>Irvine, CA</i>	type 1 diabetes, type 2 diabetes	Phase I (888) 401-3376
INT-131	InteKrin Therapeutics <i>Los Altos, CA</i>	type 2 diabetes	Phase II (650) 941-5501
<b>Intesulin™</b> insulin oral	Coremed <i>Lake Bluff, IL</i>	diabetes	Phase I (847) 772-6868
ISIS 113715	Isis Pharmaceuticals <i>Carlsbad, CA</i>	type 2 diabetes (combination therapy)	Phase II (800) 679-4747
ISIS 325568	Isis Pharmaceuticals <i>Carlsbad, CA</i>	type 2 diabetes	Phase I (800) 679-4747
JTT 654	Japan Tobacco <i>Englewood Cliffs, NJ</i>	type 2 diabetes	Phase I (201) 871-1210
K 111	Kowa Pharmaceuticals America <i>Montgomery, AL</i>	type 2 diabetes	Phase II (334) 288-1288
KRP 104	ActivX Biosciences <i>La Jolla, CA</i>	type 2 diabetes	Phase II (858) 558-5558
larazotide	Alba Therapeutics <i>Baltimore, MD</i>	type 1 diabetes (see also gastrointestinal)	Phase I (410) 319-0780
liraglutide (NN2211)	Novo Nordisk <i>Princeton, NJ</i>	type 2 diabetes	application submitted (800) 727-6500
lisofylline	DiaKine Therapeutics <i>Charlottesville, VA</i>	type 1 diabetes (newly-diagnosed)	Phase I (434) 975-2001
LP-10152	Eli Lilly <i>Indianapolis, IN</i>	type 2 diabetes	Phase I/II (800) 545-5979
LY-2189265	Eli Lilly <i>Indianapolis, IN</i>	type 2 diabetes	Phase II/III (800) 545-5979
LY-2405319	Eli Lilly <i>Indianapolis, IN</i>	type 2 diabetes	Phase II (800) 545-5979

## DIABETES, TYPE 1 AND TYPE 2

Product Name	Sponsor	Indication	Development Status
LY-2599506	Eli Lilly <i>Indianapolis, IN</i>	type 2 diabetes	Phase I (800) 545-5979
MB07803	Metabasis Therapeutics <i>La Jolla, CA</i>	type 2 diabetes	Phase II (858) 587-2770
MBX-102	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> Metabolex <i>Hayward, CA</i>	type 2 diabetes	Phase II/III (510) 293-8800
MBX-2044	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> Metabolex <i>Hayward, CA</i>	type 2 diabetes	Phase II (510) 293-8800
MBX-2982	Metabolex <i>Hayward, CA</i>	type 2 diabetes	Phase I (510) 293-8800
<b>MetControl™</b> metformin buccal	Generex Biotechnology <i>Toronto, ON</i>	type 2 diabetes	Phase II (416) 364-2551
<b>Metgluna™</b> mitiglinide/ metformin	Elixir Pharmaceuticals <i>Cambridge, MA</i>	type 2 diabetes (combination therapy)	Phase III (617) 995-7000
MK-0893	Merck <i>Whitehouse Station, NJ</i>	diabetes	Phase II (800) 672-6372
MK-0941	Merck <i>Whitehouse Station, NJ</i>	diabetes	Phase I (800) 672-6372
MK-2662	Merck <i>Whitehouse Station, NJ</i>	diabetes	Phase I (800) 672-6372
MK-4074	Merck <i>Whitehouse Station, NJ</i>	diabetes	Phase I (800) 672-6372
MK-8245	Merck <i>Whitehouse Station, NJ</i>	diabetes	Phase I (800) 672-6372
MP-513	Mitsubishi Pharma America <i>Warren, NJ</i>	type 2 diabetes	Phase I (908) 607-1950
MSDC-0160	Metabolic Solutions Development <i>Kalamazoo, MI</i>	type 2 diabetes	Phase II (616) 464-5071
<b>Nasulin™</b> insulin intranasal	CPEX Pharmaceuticals <i>Exeter, NH</i>	type 1 diabetes, type 2 diabetes	Phase II (603) 658-6100
<b>Naturlose™</b> tagatose	Spherix <i>Bethesda, MD</i>	type 2 diabetes	Phase III (301) 897-2540
NBI-6024	Neurocrine Biosciences <i>San Diego, CA</i>	type 1 diabetes	Phase II (858) 658-7600

## DIABETES, TYPE 1 AND TYPE 2

Product Name	Sponsor	Indication	Development Status
netoglitzzone	Perlegen Sciences <i>Mountain View, CA</i>	type 2 diabetes	Phase I (650) 625-4500
NN1250	Novo Nordisk <i>Princeton, NJ</i>	type 1 diabetes, type 2 diabetes	Phase II (800) 727-6500
NP-500	Napo Pharmaceuticals <i>South San Francisco, CA</i>	type 2 diabetes	Phase I (650) 616-1900
ONO-5129	Ono Pharma USA <i>Lawrenceville, NJ</i>	type 2 diabetes	Phase II (609) 219-1010
oral insulin using eligen® technology	Emisphere Technologies <i>Cedar Knolls, NJ</i>	type 2 diabetes	Phase I/II (973) 532-8000
otelixizumab <b>(Orphan Drug)</b>	Tolerx <i>Cambridge, MA</i>	type 1 diabetes (see also skin)	Phase II (617) 354-8100
PEG-encapsulated islet cell transplantation therapy	Novocell <i>San Diego, CA</i>	type 1 diabetes	Phase I/II (858) 455-3708
PF-734200	Pfizer <i>New York, NY</i>	type 2 diabetes	Phase II (860) 732-5156
PF-4325667	Pfizer <i>New York, NY</i>	diabetes	Phase I (860) 732-5156
PHX-1149 (dutogliptin)	Forest Laboratories <i>New York, NY</i> Phenomix <i>San Diego, CA</i>	type 2 diabetes	Phase III (800) 947-5227 (858) 731-5200
PPM-201	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	type 2 diabetes	Phase I (800) 934-5556
PPM-202	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	type 2 diabetes	Phase I (800) 934-5556
PPM-204 (indeglistazar)	Plexxicon <i>Berkeley, CA</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	type 2 diabetes	Phase II (510) 647-4000 (800) 934-5556
<b>Prochymal™</b> human mesenchymal stem cell therapy	Osiris Therapeutics <i>Columbia, MD</i>	type 1 diabetes (see also gastrointestinal, lung)	Phase II (443) 545-1800
pyrazinoyl-guanidine	SuperGen <i>Dublin, CA</i>	type 2 diabetes	Phase II (925) 560-0100
R1439 (aleglitazar)	Roche <i>Nutley, NJ</i>	type 2 diabetes	Phase II (973) 235-5000
R1511	Roche <i>Nutley, NJ</i>	type 2 diabetes	Phase I (973) 235-5000
R1579	Roche <i>Nutley, NJ</i>	type 2 diabetes	Phase II (973) 235-5000
R4929	Roche <i>Nutley, NJ</i>	type 2 diabetes	Phase I (973) 235-5000

## DIABETES, TYPE 1 AND TYPE 2

Product Name	Sponsor	Indication	Development Status
R7201	Roche <i>Nutley, NJ</i>	type 2 diabetes	Phase I (973) 235-5000
R7234	Roche <i>Nutley, NJ</i>	type 2 diabetes	Phase I (973) 235-5000
remogliflozin	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	type 2 diabetes	Phase II (888) 825-5249
rHuPH20	Halozyme Therapeutics <i>San Diego, CA</i>	diabetes	Phase I (858) 794-8889
rivoglitazone	Daiichi Sankyo <i>Parsippany, NJ</i>	type 2 diabetes	Phase III (973) 359-2600
RO-438857	Roche <i>Nutley, NJ</i>	type 2 diabetes	in clinical trials (973) 235-5000
SAR7226 (SGLT1/SGLT2 inhibitor)	sanofi-aventis <i>Bridgewater, NJ</i>	type 2 diabetes	Phase I (800) 633-1610
saxagliptin (DPP4 inhibitor)	AstraZeneca <i>Wilmington, DE</i> Bristol-Myers Squibb <i>Princeton, NJ</i>	diabetes	application submitted (800) 236-9933 (212) 546-4000
saxagliptin/ metformin combination therapy	AstraZeneca <i>Wilmington, DE</i>	type 2 diabetes	Phase III (800) 236-9933
sodelglitazar	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	type 2 diabetes	Phase II (888) 825-5249
SRT-2104	Sirtris Pharmaceuticals <i>Cambridge, MA</i>	type 2 diabetes	Phase I (617) 252-6920
succinobucol	AtheroGenics <i>Alpharetta, GA</i>	type 2 diabetes	Phase III (678) 336-2500
SUN E7001	Asubio Pharma <i>Rochelle Park, NJ</i>	type 2 diabetes	Phase I (201) 368-5020
SYR-472	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	type 2 diabetes	Phase II (224) 554-1200
TA-6666	Mitsubishi Pharma America <i>Warren, NJ</i>	type 2 diabetes	Phase II (908) 607-1950
TA-7284	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> Mitsubishi Pharma America <i>Warren, NJ</i>	type 2 diabetes	Phase I (800) 817-5286 (908) 607-1950
tasoglutide	Roche <i>Nutley, NJ</i>	type 2 diabetes	Phase II completed (973) 235-5000

## DIABETES, TYPE 1 AND TYPE 2

Product Name	Sponsor	Indication	Development Status
<b>Technosphere® Insulin</b> insulin inhalation	MannKind <i>Valencia, CA</i>	type 1 diabetes, type 2 diabetes	Phase III (661) 775-5300
teplizumab <b>(Orphan Drug)</b>	Eli Lilly <i>Indianapolis, IN</i> Macrogenics <i>Rockville, MD</i>	type 1 diabetes	Phase II/III (800) 545-5979 (301) 251-5172
trodusquemine	Genaera <i>Plymouth Meeting, PA</i>	type 2 diabetes	Phase I (610) 941-4020
TT-223 and epidermal growth factor analogue	Eli Lilly <i>Indianapolis, IN</i> Transition Therapeutics <i>Toronto, ON</i>	type 1 diabetes, type 2 diabetes	Phase II (800) 545-5979 (416) 260-7770
TT-223 and GLP-1 analogue	Eli Lilly <i>Indianapolis, IN</i> Transition Therapeutics <i>Toronto, ON</i>	type 1 diabetes, type 2 diabetes	Phase I (800) 545-5979 (416) 260-7770
TT-223 and metformin	Eli Lilly <i>Indianapolis, IN</i> Transition Therapeutics <i>Toronto, ON</i>	type 1 diabetes, type 2 diabetes	Phase II (800) 545-5979 (416) 260-7770
TTP355	TransTech Pharma <i>High Point, NC</i>	type 2 diabetes	Phase I (336) 841-0300
VGX-1027	VGX Pharmaceuticals <i>Blue Bell, PA</i>	type 1 diabetes (see also rheumatoid arthritis)	Phase I (267) 440-4200
<b>VIaject™</b> insulin injectable	Bidel <i>Danbury, CT</i>	type 1 diabetes, type 2 diabetes	Phase III (203) 796-5000
<b>VIAtab™</b> insulin oral sublingual	Bidel <i>Danbury, CT</i>	type 1 diabetes, type 2 diabetes	Phase I (203) 796-5000
vildagliptin/ metformin combination	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	type 2 diabetes	application submitted (888) 669-6682
XOMA052	XOMA <i>Berkeley, CA</i>	type 2 diabetes	Phase I (510) 204-7200
YM543	Astellas Pharma US <i>Deerfield, IL</i>	type 2 diabetes	Phase II (800) 727-7003

## EPILEPSY

Product Name	Sponsor	Indication	Development Status
brivaracetam <b>(Orphan Drug)</b>	UCB <i>Smyrna, GA</i>	epilepsy, myoclonic seizures	Phase III (770) 970-7500
carbamazepine intravenous	OVATION Pharmaceuticals <i>Deerfield, IL</i>	epilepsy	Phase III (847) 282-1000

## EPILEPSY

Product Name	Sponsor	Indication	Development Status
carisbamate	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	epilepsy (adjunctive treatment) (see also pain, other)	application submitted (800) 817-5286
eslicarbazepine	Sepracor <i>Marlborough, MA</i>	epilepsy	Phase III (508) 481-6700
ganaxolone	Marinus Pharmaceuticals <i>Branford, CT</i>	partial seizures (adjunctive treatment)	Phase II (203) 315-0566
ICA-105665	Icagen <i>Durham, NC</i>	epilepsy (see also pain)	Phase I (919) 941-5206
JZP-4	Jazz Pharmaceuticals <i>Palo Alto, CA</i>	epilepsy	Phase I (650) 496-3777
JZP-8	Jazz Pharmaceuticals <i>Palo Alto, CA</i>	recurrent acute repetitive seizures	Phase II (650) 496-3777
<b>Lamictal® XR™</b> lamotrigine controlled-release	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	partial seizures (adjunctive treatment) ----- tonic-clonic seizures	application submitted (888) 825-5249  Phase III (888) 825-5249
perampanel (E2007)	Eisai Medical Research <i>Ridgefield Park, NJ</i>	epilepsy (see also pain)	Phase III (888) 422-4743
retigabine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Valeant Pharmaceuticals <i>Aliso Viejo, CA</i>	partial seizures (adjunctive treatment) (see also pain)	Phase III (888) 825-5249 (800) 548-5100
retigabine sustained-release	Valeant Pharmaceuticals <i>Aliso Viejo, CA</i>	partial seizures (adjunctive treatment)	Phase I (800) 548-5100
rufinamide (E2080)	Eisai Medical Research <i>Ridgefield Park, NJ</i>	epilepsy	application submitted (888) 422-4743
SRx-502 (topiramate extended-release)	Spherics <i>Mansfield, MA</i>	epilepsy	Phase II (866) 862-4383
T-2000	Taro Pharmaceuticals U.S.A. <i>Hawthorne, NY</i>	epilepsy	Phase I (800) 544-1449
talampanel	Teva Neuroscience <i>Kansas City, MO</i>	epilepsy	Phase II completed (816) 508-5000
<b>Vanquix™</b> diazepam intramuscular	King Pharmaceuticals <i>Bristol, TN</i>	epilepsy	Phase III (800) 776-3637
<b>Vimpat®</b> lacosamide	Schwarz Pharma <i>Mequon, WI</i>	epilepsy (monotherapy) (see also osteoarthritis, pain)	Phase III (800) 558-5114
<b>Zonegran®</b> zonisamide zydys	Eisai Medical Research <i>Ridgefield Park, NJ</i>	epilepsy	application submitted (888) 422-4743

## EYE DISORDERS

Product Name	Sponsor	Indication	Development Status
AC-262271	ACADIA Pharmaceuticals <i>San Diego, CA</i> Allergan <i>Irvine, CA</i>	glaucoma	Phase I (858) 558-2871 (800) 433-8871
ACU-3223	Acucela <i>Bothell, WA</i>	age-related macular degeneration	Phase I (425) 527-3260
ACU-4429	Acucela <i>Bothell, WA</i> Otsuka America Pharmaceutical <i>Rockville, MD</i>	age-related macular degeneration (dry form)	Phase I (425) 527-3260 (800) 562-3974
AdPEDF gene therapy	GenVec <i>Gaithersburg, MD</i>	age-related macular degeneration (wet form)	Phase I (240) 632-0740
aflibercept (VEGF trap)	Bayer HealthCare Pharmaceuticals <i>Wayne, PA</i> Regeneron Pharmaceuticals <i>Tarrytown, NY</i>	age-related macular degeneration (wet-form)	Phase III (888) 842-2937 (914) 345-7400
		diabetic macular edema	Phase I (888) 842-2937 (914) 345-7400
AGN-211745	Allergan <i>Irvine, CA</i>	age-related macular degeneration	Phase II (800) 433-8871
AL-37807	Alcon Laboratories <i>Fort Worth, TX</i>	glaucoma	Phase II (800) 862-5266
ALTY-0501	Alacrity Biosciences <i>Laguna Hills, VA</i>	dry eyes	Phase II (949) 951-1348
<b>Androgen Tear</b>	Allergan <i>Irvine, CA</i>	dry eyes	Phase II (800) 433-8871
AR-102	Aerie Pharmaceuticals <i>Bridgewater, NJ</i>	glaucoma	Phase II (908) 685-0069
<b>Arxxant™</b> ruboxistaurin	Eli Lilly <i>Indianapolis, IN</i>	diabetic retinopathy	application submitted (800) 545-5979
		diabetic macular edema	Phase III (800) 545-5979
<b>Atacand®</b> candesartan cilexetil	AstraZeneca <i>Wilmington, DE</i>	diabetic retinopathy	Phase III (800) 236-9933
ATG-003 (mecamylamine ophthalmic)	CoMentis <i>South San Francisco, CA</i>	age-related macular degeneration (wet form), diabetic macular edema	Phase II (650) 869-7600
bevasiranib	Opko Health <i>Miami, FL</i>	age-related macular degeneration (wet form)	Phase III (305) 575-6000
		diabetic macular edema	Phase II (305) 575-6000

## EYE DISORDERS

Product Name	Sponsor	Indication	Development Status
bimatoprost/ timolol combination	Allergan <i>Irvine, CA</i>	glaucoma, ocular hypertension	application submitted (800) 433-8871
canakinumab	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	age-related macular degeneration (see also diabetes, lung, rheumatoid arthritis)	Phase I (888) 669-6682
CNTO-2476	Centocor <i>Horsham, PA</i>	retinitis pigmentosa	Phase I (610) 651-6000
DE104	Santen Pharmaceutical <i>Napa, CA</i> Ube America <i>New York, NY</i>	glaucoma, ocular hypertension	Phase II (707) 254-1750 (212) 813-8300
E10030	Ophthotech <i>Princeton, NJ</i>	age-related macular degeneration	Phase I (609) 945-6050
ecabet	ISTA Pharmaceuticals <i>Irvine, CA</i>	dry eyes	Phase II (949) 788-6000
fluocinolone acetone ophthalmic	Alimera Sciences <i>Alpharetta, GA</i> pSivida <i>Watertown, MA</i>	diabetic macular edema	Phase III (678) 990-5740 (617) 926-5000
		age-related macular degeneration	Phase II (678) 990-5740 (617) 926-5000
glaucoma therapeutic	Allergan <i>Irvine, CA</i>	glaucoma	Phase I (800) 433-8871
iCO 007	iCO Therapeutics <i>Vancouver, BC</i>	diabetic macular edema	Phase I (604) 602-9414
iganidipine	ISTA Pharmaceuticals <i>Irvine, CA</i>	glaucoma	Phase II (949) 788-6000
INO-8875	Inotek Pharmaceuticals <i>Beverly, MA</i>	glaucoma	Phase I (978) 232-9660
INS115644	Inspire Pharmaceuticals <i>Durham, NC</i>	glaucoma	Phase I (919) 941-9777
INS117548	Inspire Pharmaceuticals <i>Durham, NC</i>	glaucoma, ocular hypertension	Phase I (919) 941-9777
iSONEP™ sonecipzumab	Lpath <i>San Diego, CA</i>	age-related macular degeneration (wet form)	Phase I (858) 678-0800
JSM6427	Jerini Ophthalmic <i>New York, NY</i> PR Pharmaceuticals <i>Fort Collins, CO</i>	age-related macular degeneration	Phase I (212) 408-0450
Lantus® insulin glargine	sanofi-aventis <i>Bridgewater, NJ</i>	diabetic retinopathy	application submitted (800) 633-1610
latanoprost (new formulation)	ISTA Pharmaceuticals <i>Irvine, CA</i>	glaucoma	Phase I (949) 788-6000

## EYE DISORDERS

Product Name	Sponsor	Indication	Development Status
LD22-4	Advanced Refractive Technologies <i>San Clemente, CA</i>	age-related macular degeneration (wet form)	Phase I (949) 940-1300
<b>Lucentis™</b> ranibizumab	Genentech <i>South San Francisco, CA</i>	diabetic macular edema, retinal vascular occlusion	Phase III (650) 225-1000
<b>Macugen®</b> pegaptanib	OSI Pharmaceuticals <i>Melville, NY</i>	diabetic macular edema, diabetic retinopathy	Phase III (631) 962-2000
		retinal vascular occlusion	Phase II completed (631) 962-2000
Moli1901	Lantibio <i>Chapel Hill, NC</i>	dry eyes	Phase II (919) 960-0217
Nova63035	Novagali Pharma <i>Cedex, France</i>	diabetic macular edema	Phase I
NP50301	Nascent Pharmaceuticals <i>Burlingame, CA</i>	dry eye syndrome in postmenopausal women	Phase II (415) 967-1998
NT-501	Neurotech USA <i>Lincoln, RI</i>	retinitis pigmentosa	Phase II/III (401) 333-3880
		age-related macular degeneration	Phase II (401) 333-3880
olmesartan ophthalmic	Santen Pharmaceutical <i>Napa, CA</i>	glaucoma, ocular hypertension	Phase II (707) 254-1750
OPC-12759 (rebamipide)	Acucela <i>Bothell, WA</i> Otsuka America Pharmaceutical <i>Rockville, MD</i>	dry eyes	Phase III (425) 527-3260 (800) 562-3974
OT-551	Othera Pharmaceuticals <i>Exton, PA</i>	cataracts (prevention), dry age-related macular atrophy	Phase II (877) 551-8240
		age-related macular degeneration (wet form)	Phase I (877) 551-8240
OT-730	Othera Pharmaceuticals <i>Exton, PA</i>	glaucoma	Phase I/II (877) 551-8240
pazopanib ophthalmic	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	age-related macular degeneration	Phase II (888) 825-5249
PF-4217329	Pfizer <i>New York, NY</i>	glaucoma	Phase II (860) 732-5156
<b>Photrex™</b> rostaporfin	Miravant Medical Technologies <i>Santa Barbara, CA</i>	age-related macular degeneration (wet-form)	application submitted (888) 768-5501
pimecrolimus ophthalmic	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	dry eyes	Phase II (888) 669-6682
<b>Posurdex®</b> dexamethasone	Allergan <i>Irvine, CA</i>	diabetic macular edema, retinal edema	Phase III (800) 433-8871

## EYE DISORDERS

Product Name	Sponsor	Indication	Development Status
POT-4	Potentia Pharmaceuticals <i>Louisville, KY</i>	age-related macular degeneration (wet form)	Phase I (502) 569-1053
<b>Prolacria</b> <sup>TM</sup> diquafosol tetrasodium	Allergan <i>Irvine, CA</i> Inspire Pharmaceuticals <i>Durham, NC</i>	dry eyes	application submitted (800) 433-8871 (919) 941-9777
<b>Retane</b> <sup>®</sup> anecortave acetate for depot suspension	Alcon Laboratories <i>Fort Worth, TX</i>	glaucoma	Phase II/III (800) 862-5266
rivoglitazone ophthalmic	Santen Pharmaceutical <i>Napa, CA</i>	dry eyes	Phase II (707) 254-1750
RTP-801i	Pfizer <i>New York, NY</i>	diabetic macular edema	Phase II (860) 732-5156
		age-related macular degeneration	Phase I/II (860) 732-5156
sirolimus ophthalmic	MacuSight <i>Union City, CA</i>	diabetic macular edema	Phase II (510) 400-1440
		age-related macular degeneration (wet form)	Phase I (510) 400-1440
ST-602 (fenretinide)	Sirion Therapeutics <i>Tampa, FL</i>	age-related macular degeneration (dry form)	Phase II (813) 496-7325
ST-603 (ciclosporin A ophthalmic)	Sirion Therapeutics <i>Tampa, FL</i>	dry eyes	Phase III completed (813) 496-7325
TB-403	Roche <i>Nutley, CA</i>	age-related macular degeneration	Phase I (973) 235-5000
TG-100801	TargeGen <i>San Diego, CA</i>	age-related macular degeneration	Phase II (858) 678-0760
travoprost/timolol fixed combination	Alcon Laboratories <i>Fort Worth, TX</i>	glaucoma	application submitted (800) 862-5266
<b>Vexol</b> <sup>®</sup> rimexolone	Schering-Plough <i>Kenilworth, TX</i>	dry eyes	Phase II (908) 298-4000
<b>Vitreosolve</b> <sup>TM</sup>	Vitreoretinal Technologies <i>Irvine, CA</i>	diabetic retinopathy	Phase III (877) 478-3301
Y39983	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	glaucoma	Phase I (888) 669-6682
<b>Zinthionein</b> <sup>TM</sup> zinc monocysteine	Adeona Pharmaceuticals <i>Ann Arbor, MI</i>	age-related macular degeneration (dry form)	Phase III (734) 332-7800

## GASTROINTESTINAL DISORDERS

Product Name	Sponsor	Indication	Development Status
561679 (CRF receptor 1 antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Neurocrine Biosciences <i>San Diego, CA</i>	irritable bowel syndrome (see also depression)	Phase I (888) 825-5249 (858) 617-7600
876008 (CRF receptor 1 antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Neurocrine Biosciences <i>San Diego, CA</i>	irritable bowel syndrome (see also depression)	Phase II (888) 825-5249 (858) 617-7600
1399686	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	irritable bowel syndrome	Phase I (888) 825-5249
ABT-874	Abbott Laboratories <i>Abbott Park, IL</i>	Crohn's disease (see also skin)	Phase II (847) 937-6100
<b>Aciphex®</b> rabeprazole extended-release	Eisai Medical Research <i>Ridgefield Park, NJ</i>	gastroesophageal reflux disease (GERD)	Phase III (888) 422-4743
alicaforsen <b>(Orphan Drug)</b>	Atlantic Pharmaceuticals <i>Cambridge, MA</i>	Crohn's disease, pouchitis, ulcerative colitis	Phase III
apilimod	Synta Pharmaceuticals <i>Lexington, MA</i>	Crohn's disease (see also rheumatoid arthritis)	Phase II (781) 274-8200
arbaclofen placarbil	XenoPort <i>Santa Clara, CA</i>	GERD	Phase II (408) 616-7200
asimadoline	Tioga Pharmaceuticals <i>San Diego, CA</i>	irritable bowel syndrome, post-operative ileus	Phase II (858) 677-6077
AST-120	Ocera Therapeutics <i>San Diego, CA</i>	Crohn's disease	Phase III (858) 436-3900
		GERD, pouchitis	Phase II (858) 436-3900
ATI-7505	ARYx Therapeutics <i>Fremont, CA</i>	GERD	Phase II completed (510) 585-2200
ATL-2502	Prometheus Laboratories <i>San Diego, CA</i>	ulcerative colitis	Phase II (888) 892-8391
AZD1386	AstraZeneca <i>Wilmington, DE</i>	GERD (see also pain)	Phase I (800) 236-9933
AZD2066	AstraZeneca <i>Wilmington, DE</i>	GERD (see also pain)	Phase I (800) 236-9933
AZD3355	AstraZeneca <i>Wilmington, DE</i>	GERD	Phase II (800) 236-9933
balsalazide (twice-daily dosing)	Salix Pharmaceuticals <i>Morrisville, NC</i>	ulcerative colitis	application submitted (919) 862-1000
budesonide controlled-release	Cosmo Pharmaceuticals <i>Lainate, Italy</i>	ulcerative colitis	Phase III
CCX-282	ChemoCentryx <i>Mountain View, CA</i> GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	Crohn's disease	Phase II/III (888) 825-5249
		ulcerative colitis	Phase I (888) 825-5249

# GASTROINTESTINAL DISORDERS

Product Name	Sponsor	Indication	Development Status
CP-690550	Pfizer <i>New York, NY</i>	Crohn's disease, irritable bowel disease (see also rheumatoid arthritis, skin)	Phase II (860) 732-5156
crofelemer	Napo Pharmaceuticals <i>South San Francisco, CA</i>	diarrhea-predominant irritable bowel syndrome	Phase II (650) 616-1900
DDP225	Dynogen Pharmaceuticals <i>Waltham, MA</i>	irritable bowel syndrome with diarrhea (see also bladder)	Phase II (781) 839-5100
delmitide	Genzyme <i>Cambridge, MA</i>	Crohn's disease, ulcerative colitis	Phase I (617) 252-7500
dexlansoprazole	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	GERD	application submitted (224) 554-6500
dextofisopam	Pharmos <i>Iselin, NJ</i>	irritable bowel syndrome	Phase II (732) 452-9556
doramapimod (BIRB796)	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	Crohn's disease (see also rheumatoid arthritis, skin)	Phase II (203) 798-9988
E3210	Eisai Medical Research <i>Ridgefield Park, NJ</i>	irritable bowel syndrome	Phase I (888) 422-4743
E3710	Eisai Medical Research <i>Ridgefield Park, NJ</i>	GERD	Phase I (888) 422-4743
eicosapentaenoic acid/ docosahexaenoic acid	Tillotts Pharma <i>Ziefen, Switzerland</i>	Crohn's disease	Phase III
<b>Gattex™</b> teduglutide <b>(Orphan Drug)</b>	NPS Pharmaceuticals <i>Salt Lake City, UT</i>	short bowel syndrome	Phase III (801) 583-4939
		Crohn's disease	Phase II (801) 583-4939
GERD treatment extended-release formulation	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> Depomed <i>Menlo Park, CA</i>	GERD	Phase I (203) 798-9988
golimumab	Centocor <i>Horsham, PA</i> Medarex <i>Princeton, NJ</i>	ulcerative colitis (see also rheumatoid arthritis, skin)	Phase II/III (610) 651-6000
HE-3286	Hollis-Eden Pharmaceuticals <i>San Diego, CA</i>	ulcerative colitis (see also diabetes, rheumatoid arthritis)	Phase I/II (858) 587-9333
HMPL-004	Hutchison MediPharma <i>Shanghai, China</i>	Crohn's disease	Phase II
<b>Humira®</b> adalimumab	Abbott Laboratories <i>Abbott Park, IL</i>	ulcerative colitis	Phase III (847) 937-6100

## GASTROINTESTINAL DISORDERS

Product Name	Sponsor	Indication	Development Status
ilaprazole	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	GERD	Phase II (224) 554-6500
larazotide	Alba Therapeutics <i>Baltimore, MD</i>	Crohn's disease, irritable bowel syndrome (see also diabetes)	Phase I (410) 319-0780
linaclotide	Forest Laboratories <i>New York, NY</i> Ironwood Pharmaceuticals <i>Cambridge, MA</i>	chronic constipation, constipation-predominant irritable bowel syndrome	Phase III (800) 678-1605
LX-1031	Lexicon Pharmaceuticals <i>The Woodlands, TX</i>	irritable bowel syndrome	Phase I completed (281) 863-3000
MDX-1100	Medarex <i>Princeton, NJ</i>	ulcerative colitis (see also rheumatoid arthritis)	Phase II (609) 430-2880
methylnaltrexone	Progenics Pharmaceuticals <i>Tarrytown, NY</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	post-operative ileus (IV formulation)	Phase III (914) 789-2814 (800) 936-5556
		constipation (oral formulation)	Phase II (914) 789-2814 (800) 936-5556
metoclopramide rapidly disintegrating tablet	Salix Pharmaceuticals <i>Morrisville, NC</i> Wilmington Pharmaceuticals <i>Wilmington, NC</i>	diabetic gastroparesis, GERD	application submitted (919) 862-1000 (910) 509-0097
mitemcinal	Chugai Pharma USA <i>Bedminster, NJ</i>	diabetic gastroparesis, gastroparesis, irritable bowel syndrome	Phase II (908) 947-2700
MLN-0002	Millennium Pharmaceuticals <i>Cambridge, MA</i>	Crohn's disease, ulcerative colitis	Phase II (800) 390-5663
<b>Neumega</b> <sup>®</sup> oprelvekin	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	Crohn's disease (see also rheumatoid arthritis)	Phase III (800) 938-5556
NI-0401	EMD Serono <i>Rockland, MA</i> NovImmune <i>Geneva, Switzerland</i>	Crohn's disease	Phase I/II (800) 812-8088
nitazoxanide	Romark Laboratories <i>Tampa, FL</i>	Crohn's disease	in clinical trials (813) 282-8544
NKTR-118	Nektar Therapeutics <i>San Carlos, CA</i>	constipation	Phase II (650) 631-3100
<b>orBec</b> <sup>™</sup> beclomethasone dipropionate	DOR BioPharma <i>Lake Forest, IL</i>	gastrointestinal graft vs. host disease	application submitted (847) 573-8990
		gastrointestinal graft vs. host disease (prevention)	Phase II (847) 573-8990

## GASTROINTESTINAL DISORDERS

Product Name	Sponsor	Indication	Development Status
<b>Orencia®</b> abatacept	Bristol-Myers Squibb <i>Princeton, NJ</i>	Crohn's disease, ulcerative colitis	Phase II/III (212) 546-4000
<b>Paxil®</b> paroxetine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	irritable bowel syndrome	Phase II (888) 825-5249
PB-008	Inflabloc Pharmaceuticals <i>Salt Lake City, UT</i>	Crohn's disease (see also lung)	Phase I (801) 303-1860
PF-885706	Pfizer <i>New York, NY</i>	GERD	Phase II (860) 732-5156
PF-2391677	Pfizer <i>New York, NY</i>	GERD	Phase I (860) 732-5156
PF-4548043 (KOS 2187)	Kosan Biosciences <i>Hayward, CA</i> Pfizer <i>New York, NY</i>	diabetic gastroparesis, GERD	Phase I (860) 732-5156
<b>Probactrix®</b> escherichia coli M17	BioBalance <i>New York, NY</i>	GERD	Phase III
		pouchitis	Phase I/II
<b>Prochymal™</b> human mesenchymal stem cell therapy	Osiris Therapeutics <i>Columbia, MD</i>	Crohn's disease (see also diabetes, lung)	Phase III (443) 545-1800
pumosetrag	Dynogen Pharmaceuticals <i>Waltham, MA</i>	constipation-predominant irritable bowel syndrome	Phase II (781) 839-5100
		nocturnal GERD	Phase I (781) 839-5100
<b>Rezular™</b> arverapamil	AGI Therapeutics <i>Columbia, MD</i>	diarrhea-predominant irritable bowel syndrome	Phase III (443) 285-0095
RWJ-68023	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	irritable bowel syndrome	Phase I (800) 817-0000
SAR102779 (NK2 antagonist)	sanofi-aventis <i>Bridgewater, NJ</i>	irritable bowel syndrome (see also depression)	Phase I (800) 633-1610
<b>Simulect®</b> basiliximab	Cermion Pharmaceuticals <i>South San Francisco, CA</i>	ulcerative colitis	Phase II (650) 827-4000
solabegron	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	irritable bowel syndrome (see also bladder)	Phase I (888) 825-5249
SP-304	Synergy Pharmaceuticals <i>New York, NY</i>	constipation-predominant irritable bowel syndrome	Phase I (212) 297-0020
TD-5108	Theravance <i>South San Francisco, CA</i>	constipation	Phase II (877) 275-8479
tetomilast	Otsuka America Pharmaceutical <i>Rockville, MD</i>	ulcerative colitis (see also lung)	Phase III completed (800) 562-3974

## GASTROINTESTINAL DISORDERS

Product Name	Sponsor	Indication	Development Status
TTF3	The GI Company <i>Framingham, MA</i>	ulcerative colitis	in clinical trials (508) 628-9225
ustekinumab	Centocor <i>Horsham, PA</i> Medarex <i>Princeton, NJ</i>	Crohn's disease (see also skin)	Phase II (610) 651-6000
<b>VECAM™</b> enhanced action proton pump inhibitor	Vecta <i>Rehovot, Israel</i>	GERD	Phase II
<b>Xifaxan™</b> rifaximin	Salix Pharmaceuticals <i>Morrisville, NC</i>	irritable bowel syndrome	Phase II (919) 862-1000

## LUNG/RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
552-02	Parion Sciences <i>Durham, NC</i>	chronic bronchitis	Phase II (919) 313-1180
159802 (long-acting beta2 agonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma, chronic obstructive pulmonary disease (COPD)	Phase II (888) 825-5249
256066 (PDE IV inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma, COPD	Phase II (888) 825-5249
573719 (muscarinic receptor antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase II (888) 825-5249
610677	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase I (888) 825-5249
642444 (long-acting beta2 agonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma, COPD	Phase II (888) 825-5249
656933 (IL8 antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase I (888) 825-5249
679586 (mAb)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma	Phase I/II (888) 825-5249
681323 (p38 kinase inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD (see also pain, rheumatoid arthritis)	Phase II (888) 825-5249
856553 (p38 MAP kinase inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD (see also depression, rheumatoid arthritis)	Phase II (888) 825-5249
870086 (glucocorticoid receptor agonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma	Phase II (888) 825-5249

## LUNG/RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
961081	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase II (888) 825-5249
1160724 (muscarinic receptor antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase I (888) 825-5249
ABN912	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	asthma, COPD	Phase I (888) 669-6682
<b>ACAM-FLU-A™</b>	Acambis <i>Cambridge, MA</i>	influenza virus infections (prevention)	Phase I (617) 761-4200
aclidinium bromide	Forest Laboratories <i>New York, NY</i>	COPD	Phase III (800) 678-1605
AER-002	Aerovance <i>Berkeley, CA</i>	COPD	Phase II (510) 549-5500
AERAS-402	Aeras Global TB Vaccine Foundation <i>Rockville, MD</i> Crucell <i>Leiden, The Netherlands</i>	tuberculosis	Phase I (301) 547-2900
<b>Aflunov™</b> influenza A virus H5N1 vaccine	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	influenza A virus H5N1 subtype (prevention)	Phase II (888) 669-6682
AIR-645	Altair Therapeutics <i>San Francisco, CA</i>	asthma	Phase I (415) 541-8600
<b>Alferon® LDO</b> interferon-alpha-n3	Hemispherx Biopharma <i>Philadelphia, PA</i>	influenza virus infections	Phase I (215) 988-0080
ALKS-27	Alkermes <i>Cambridge, MA</i> Indevus Pharmaceuticals <i>Lexington, MA</i>	COPD	Phase II (617) 494-0171 (781) 861-8444
AMG 317	Amgen <i>Thousand Oaks, CA</i>	asthma	Phase II (800) 772-6436
AMG 853	Amgen <i>Thousand Oaks, CA</i>	asthma	Phase I (800) 772-6436
anrukinzumab	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	asthma	Phase II (800) 934-5556
anti-IL13 mAb	Genentech <i>South San Francisco, CA</i>	asthma	Phase I (650) 225-1000
AP768	Actimis Pharmaceuticals <i>San Diego, CA</i>	asthma	Phase I (858) 458-1890
APT-001	APT Pharmaceuticals <i>Burlingame, CA</i>	asthma	Phase II (650) 931-1666
ASM8	Topigen Pharmaceuticals <i>Montreal, QC</i>	asthma	Phase II (514) 868-0077
<b>Asmanex®</b> mometasone	Schering-Plough <i>Kenilworth, NJ</i>	COPD	application submitted (908) 298-4000

## LUNG/RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
ATL-844	PGxHealth <i>New Haven, CT</i>	asthma (see also diabetes)	Phase II (877) 274-9432
<b>Augmentin XR®</b> amoxicillin/ clavulanic acid controlled-release	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	acute exacerbations of chronic bronchitis	Phase III (888) 825-5249
<b>Avandia®</b> rosiglitazone	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma (see also Alzheimer's, diabetes)	Phase II/III (888) 825-5249
AVE0675 (TLR9 agonist)	sanofi-aventis <i>Bridgewater, NJ</i>	asthma	Phase I (800) 633-1610
AVP 13358	Avanir Pharmaceuticals <i>Aliso Viejo, CA</i>	allergic asthma	Phase I (949) 389-6700
AVX502	AlphaVax <i>Rsch. Triangle Park, NC</i>	influenza virus infections	Phase I (919) 595-0400
AZD1236	AstraZeneca <i>Wilmington, DE</i>	COPD	Phase I (800) 236-9933
AZD1981	AstraZeneca <i>Wilmington, DE</i>	asthma	Phase II (800) 236-9933
AZD3199	AstraZeneca <i>Wilmington, DE</i>	asthma, COPD	Phase I (800) 236-9933
AZD4818	AstraZeneca <i>Wilmington, DE</i>	COPD	Phase I (800) 236-9933
AZD5904	AstraZeneca <i>Wilmington, DE</i>	COPD	Phase I (800) 236-9933
AZD9668	AstraZeneca <i>Wilmington, DE</i>	COPD	Phase I (800) 236-9933
<b>Azmacort® HFA</b> triamcinolone acetone hydrofluoroalkane inhalation	Abbott Laboratories <i>Abbott Park, IL</i>	asthma	Phase III (847) 937-6100
bedoradrine	Kissei Pharmaceutical <i>Matsumoto, Japan</i> MediciNova <i>San Diego, CA</i>	moderate to severe stable asthma, status asthmatics	Phase II (858) 373-1500
BI-1744 CL	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	asthma, COPD	Phase II (800) 243-0127
BIO-11006	BioMarck Pharmaceuticals <i>Raleigh, NC</i>	COPD	Phase I
BIW-8405	BioWa <i>Princeton, NJ</i> MedImmune <i>Gaithersburg, MD</i>	asthma	Phase I (609) 734-3420 (301) 298-0000
canakinumab	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	COPD (see also eye, diabetes, rheumatoid arthritis)	Phase I/II (888) 669-6682

## LUNG/RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
carmoterol	Chiesi Pharmaceuticals <i>Rockville, MD</i>	COPD	Phase II (301) 424-2661
CAT-354	MedImmune <i>Gaithersburg, MD</i>	asthma	Phase I (301) 298-0000
ceftaroline fosamil	Cerexa <i>Alameda, CA</i>	community-acquired pneumonia	Phase III (510) 747-3900
ceftobiprole medocaril	Basilea Pharmaceutica <i>Basel, Switzerland</i> Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	community-acquired pneumonia, nosocomial pneumonia	Phase III (800) 817-5286
CEM-101	Cempra Pharmaceuticals <i>Chapel Hill, NC</i> Optimer Pharmaceuticals <i>San Diego, CA</i>	community-acquired pneumonia	Phase I completed (919) 467-1716 (858) 909-0736
cethromycin	Advanced Life Sciences <i>Woodridge, IL</i>	mild to moderate community-acquired pneumonia	application submitted (630) 739-6744
CHF-5188	Chiesi Pharmaceuticals <i>Rockville, MD</i>	asthma, COPD	Phase II (301) 424-2661
CS-8958	Biota <i>Notting Hill, Australia</i> Daiichi Sankyo <i>Parsippany, NJ</i>	influenza virus infections	Phase I (973) 359-2600
CVT-6883	CV Therapeutics <i>Palo Alto, CA</i>	asthma	Phase I (650) 384-8500
darapladib	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma	Phase I (888) 825-5249
darotropium bromide	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase II (888) 825-5249
DAS-181	NexBio <i>San Diego, CA</i>	influenza virus infections	Phase I (858) 452-2631
<b>Daxas</b> <sup>®</sup> roflumilast	Nycomed US <i>Melville, NY</i>	asthma, COPD	Phase III (631) 454-7677
<b>Doribax</b> <sup>™</sup> doripenem	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	nosocomial pneumonia	application submitted (800) 817-5286
DSP-3025	AstraZeneca <i>Wilmington, DE</i> Dainippon Sumitomo Pharma America <i>Fort Lee, NJ</i>	asthma	Phase I (800) 236-9933
EDP-420	Enanta Pharmaceuticals <i>Watertown, MA</i>	community-acquired pneumonia	Phase II (617) 607-0800

## LUNG/RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
elastase inhibitor	Bayer HealthCare Pharmaceuticals Wayne, NJ	COPD	Phase I (888) 842-2937
epinastine	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	asthma	Phase I (800) 243-0127
erdosteine	Adams Respiratory Therapeutics Parsippany, NJ	bronchitis	Phase II (973) 404-2600
fandosentan	Pfizer New York, NY	COPD	Phase I/II (860) 732-5156
<b>FluBIØK™</b> rHAO recombinant influenza vaccine	Protein Sciences Meriden, CT	influenza virus infections (prevention)	application submitted (203) 686-0800
flu cell vaccine (new production method)	sanofi pasteur Swiftwater, PA	influenza	Phase II (570) 839-4267
flu micro-injection vaccine (new delivery)	sanofi pasteur Swiftwater, PA	influenza	Phase II (570) 839-4267
flu pandemic vaccine (H7 cell culture, low dose)	sanofi pasteur Swiftwater, PA	influenza	Phase I (570) 839-4267
<b>Flutiform™</b> formoterol/ fluticasone propionate	Abbott Laboratories Abbott Park, IL SkyePharma San Diego, CA	asthma	Phase III (858) 625-2424
flu vaccine (new formulation)	sanofi pasteur Swiftwater, PA	influenza virus infections	Phase III (570) 839-4267
H5N1 avian influenza intranasal vaccine	MedImmune Gaithersburg, MD National Institute of Allergy and Infectious Diseases Bethesda, MD	influenza virus infections	Phase I (301) 298-0000
H5N1 influenza virus vaccine	Baxter International Deerfield, IL	influenza A virus H5N1 subtype (prevention)	Phase I (800) 422-9837
H5N1 influenza virus vaccine	Novavax Rockville, MD	influenza A virus H5N1 subtype (prevention)	Phase II (240) 268-2000
H5N1 pre-pandemic influenza virus vaccine	GlaxoSmithKline Rsch. Triangle Park, NC	influenza A virus H5N1 subtype (prevention, pre-pandemic use)	Phase I/II (888) 825-5249
HAE 1	Genentech South San Francisco, CA	allergic asthma	Phase II (650) 225-1000

## LUNG/RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
IC31 (influenza vaccine)	Intercell USA <i>Gaithersburg, MD</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	influenza virus infections (prevention)	Phase I (301) 556-4500 (888) 825-5249
IMA-026	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	asthma	Phase I (800) 238-5556
inactivated split-trivalent seasonal influenza vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	influenza virus infections in the elderly (prevention)	Phase III (888) 825-5249
indacaterol (QAB149)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	asthma, COPD	Phase III (888) 669-6682
indacaterol/ mometasone (QMF149)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	asthma, COPD	Phase II (888) 669-6682
influenza virus DNA vaccine	Vical <i>San Diego, CA</i>	influenza A virus H5N1 subtype (prevention)	Phase I (858) 646-1100
influenza virus-like particle vaccine	Novavax <i>Rockville, MD</i>	influenza virus infections (prevention)	Phase II (240) 268-2000
influenza virus vaccine	Antigen Express <i>Worcester, MA</i>	influenza virus infections	Phase I (508) 852-8783
influenza virus vaccine	Solvay Pharmaceuticals <i>Marietta, GA</i>	influenza virus infections	Phase I (770) 772-8200
influenza virus vaccine intranasal	Vaxin <i>Birmingham, AL</i>	influenza virus infections	Phase I (205) 909-3751
influenza virus vaccine (rNA)	Protein Sciences <i>Meridien, CT</i>	influenza virus infections	Phase II (203) 686-0800
influenza virus vaccine (subunit vaccine)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	influenza virus infections	Phase II (888) 825-5249
influenza virus vaccine (transdermal)	Intercell USA <i>Gaithersburg, MD</i>	influenza virus infections	Phase I/II (301) 556-4500
INV102	Inverseon <i>San Francisco, CA</i>	asthma	Phase II (415) 440-7400
JNJ-18054478	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	asthma	Phase I (800) 817-5286
KB200	KaloBios Pharmaceuticals <i>South San Francisco, CA</i>	asthma (see also rheumatoid arthritis)	Phase I/II (650) 243-3100
mannitol inhalation diagnostic	Pharmaxis <i>Exton, PA</i>	asthma (diagnosis)	Phase III completed (610) 363-5120
MAP0005	MAP Pharmaceuticals <i>Mountain View, CA</i>	asthma	Phase II (650) 386-3100

## LUNG/RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
mepolizumab (anti-IL5 MAb)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma	Phase II (888) 825-5249
milveterol	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Theravance <i>South San Francisco, CA</i>	asthma, COPD	Phase II (888) 825-5249
MK-2764	Merck <i>Whitehouse Station, NJ</i> Paratek Pharmaceuticals <i>Boston, MA</i>	community-acquired pneumonia	Phase I (800) 672-6372 (617) 275-0040
mometasone/ formoterol combination	Novartis Pharmaceuticals <i>East Hanover, NJ</i> Schering-Plough <i>Kenilworth, NJ</i>	asthma, COPD	Phase III (888) 669-6682 (908) 298-4000
Mtb72F/AS02A	Aeras Global TB Vaccine Foundation <i>Rockville, MD</i> GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	tuberculosis	Phase II (301) 547-2900 (888) 825-5249
N30-201	N30 Pharma <i>Boulder, CO</i>	asthma, COPD	Phase I
<b>Naturasone™</b> EPI-12323	EpiGenesis Pharmaceuticals <i>Cranbury, NJ</i>	asthma, COPD	Phase II (609) 409-6080
NKTR-061 (amikacin inhalation)	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> Nektar Therapeutics <i>San Carlos, CA</i>	nosocomial pneumonia (adjunctive treatment)	Phase II (888) 842-2937 (650) 631-3100
NVA237	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	COPD	Phase II (888) 825-5249
oglemilast	Forest Laboratories <i>New York, NY</i> Glenmark Pharmaceuticals <i>Princeton, NJ</i>	asthma, COPD	Phase II (800) 947-5227 (609) 514-1444
<b>Optaflu®</b> influenza virus vaccine	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	influenza virus infections	Phase I/II (888) 669-6682
oral sodium cromoglicate	Emisphere Technologies <i>Cedar Knolls, NJ</i>	asthma	Phase I (973) 532-8000
PA-824 <b>(Orphan Drug)</b>	Aeras Global TB Vaccine Foundation <i>Rockville, MD</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	tuberculosis	Phase II (301) 547-2900 (888) 669-6682
paclitaxel	Angiotech Pharmaceuticals <i>Vancouver, BC</i>	emphysema (see also rheumatoid arthritis, skin)	in clinical trials (604) 221-7676

## LUNG/RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
palovarotene	Roche <i>Nutley, NJ</i>	emphysema	Phase II (973) 235-5000
pandemic influenza vaccine	Novartis Pharmaceuticals <i>East Hanover, NJ</i> National Institute of Allergy and Infectious Diseases <i>Bethesda, MD</i>	influenza virus infections	Phase II (888) 669-6682
PB-008	Inflabloc Pharmaceuticals <i>Salt Lake City, UT</i>	asthma (see also gastrointestinal)	Phase II (801) 303-1860
peramivir	BioCryst Pharmaceuticals <i>Birmingham, AL</i>	influenza virus infections	Phase II (205) 444-4600
PF-489791	Pfizer <i>New York, NY</i>	COPD	Phase I (860) 732-5156
PF-610355	Pfizer <i>New York, NY</i>	asthma	Phase II (860) 732-5156
		----- COPD	Phase I (860) 732-5156
PF-3526299	Pfizer <i>New York, NY</i>	asthma	Phase I (860) 732-5156
PF-3635659	Pfizer <i>New York, NY</i>	COPD	Phase I (860) 732-5156
PF-3715455	Pfizer <i>New York, NY</i>	COPD	Phase I (860) 732-5156
PF-3893787	Pfizer <i>New York, NY</i>	asthma	Phase I (860) 732-5156
PF-4191834	Pfizer <i>New York, NY</i>	asthma (see also pain)	Phase I (860) 732-5156
PF-4522625 (influenza virus DNA vaccine)	Pfizer <i>New York, NY</i>	influenza virus infections	Phase I (860) 732-5156
PGX-100	ParinGenix <i>Tucson, AZ</i>	COPD	Phase II
PH-797804	Pfizer <i>New York, NY</i>	COPD (see also pain, rheumatoid arthritis)	Phase II (860) 732-5156
pitrakinra	Aerovance <i>Berkeley, CA</i>	acute asthma	Phase II (510) 549-5500
<b>Prochymal™</b> human mesenchymal stem cell therapy	Osiris Therapeutics <i>Columbia, MD</i>	COPD (see also diabetes, gastrointestinal)	Phase II (443) 545-1800
QAE397	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	asthma	Phase II (888) 669-6682
QAP642	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	asthma	Phase I (888) 669-6682

## LUNG/RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
QAT370	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	COPD	Phase II (888) 669-6682
QAX935	Idera Pharmaceuticals <i>Cambridge, MA</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	allergic asthma	Phase I (617) 679-5592 (888) 669-6682
QVA149	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	COPD	Phase II (888) 825-5249
R343	Pfizer <i>New York, NY</i>	allergic asthma	Phase I (860) 732-5156
R1671	Roche <i>Nutley, NJ</i>	asthma	Phase I (973) 235-5000
R7103	Roche <i>Nutley, NJ</i>	COPD	Phase I (973) 235-5000
R(+) zileuton	Critical Therapeutics <i>Lexington, MA</i>	asthma	Phase I (781) 402-5700
radezolid	Rib-X Pharmaceuticals <i>New Haven, CT</i>	community-acquired pneumonia	Phase II (203) 624-5606
recombinant <i>S. pneumoniae</i> vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	<i>Streptococcus pneumoniae</i> prophylaxis in the elderly	Phase I (888) 825-5249
<b>Remicade</b> <sup>®</sup> infliximab	Centocor <i>Horsham, PA</i>	asthma, COPD	Phase II (610) 651-6000
SAR389644 (DP1 antagonist)	sanofi-aventis <i>Bridgewater, NJ</i>	asthma	Phase I (800) 633-1610
SCH-527123	Schering-Plough <i>Kenilworth, NJ</i>	COPD	Phase II (908) 298-4000
seasonal influenza virus vaccine	Baxter International <i>Deerfield, IL</i>	influenza virus infections	Phase III (800) 422-9837
senicapoc	Icagen <i>Durham, NC</i>	asthma	Phase I (919) 941-5206
<b>Serevent</b> <sup>®</sup> salmeterol MDI dose counter	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma, COPD	Phase III (888) 669-6682
<b>Singulair</b> <sup>®</sup> montelukast	Merck <i>Whitehouse Station, NJ</i>	acute asthma	Phase III (800) 672-6372
SMP-028	Dainippon Sumitomo Pharma America <i>Fort Lee, NJ</i>	asthma	Phase I (201) 592-2050
SQ109	Sequella <i>Rockville, MD</i>	tuberculosis	Phase I (301) 762-7776
<b>Symbicort</b> <sup>®</sup> pMDI budesonide and formoterol	AstraZeneca <i>Wilmington, DE</i>	COPD	application submitted (800) 236-9933

## LUNG/RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
T705	Toyama USA New York, NY	influenza virus infections	Phase I
tacrolimus	Astellas Pharma USA Deerfield, IL	asthma (see also other)	Phase II (800) 727-7003
telavancin	Theravance South San Francisco, CA	nosocomial pneumonia	Phase III (877) 275-8479
tetomilast	Otsuka America Pharmaceutical Rockville, MD	COPD (see also gastrointestinal)	Phase II (800) 562-3974
tifacogin	Novartis Pharmaceuticals East Hanover, NJ	community-acquired pneumonia	Phase III (888) 669-6682
TMC-207	Tibotec Yardley, PA	tuberculosis	Phase II (609) 730-7500
TPI-1100	Topigen Pharmaceuticals Montreal, QC	COPD	Phase I (514) 868-0077
tuberculosis vaccine	sanofi pasteur Swiftwater, PA	tuberculosis prevention	Phase I (570) 839-4267
<b>Tygacil™</b> tigecycline	Wyeth Pharmaceuticals Collegeville, PA	community-acquired pneumonia	application submitted (800) 238-5556
V512	Merck Whitehouse Station, NJ	influenza virus infections	Phase I (800) 672-6372
VAX102	VaxInnate Cranbury, NJ	influenza A virus infections (prevention)	Phase I (609) 860-2260
VAX125	VaxInnate Cranbury, NJ	influenza A virus infections	Phase I (609) 860-2260
<b>Veramyst™</b> fluticasone furoate	GlaxoSmithKline Rsch. Triangle Park, NC	asthma, COPD	Phase II (888) 825-5249
<b>Xopenex®</b> levosalbutamol and ipratropium inhalation solution	Arrow International Reading, PA Sepracor Marlborough, MA	COPD	Phase II (508) 481-6700
zanamivir intravenous	GlaxoSmithKline Rsch. Triangle Park, NC	influenza virus infections in seriously ill patients	in clinical trials (888) 825-5249
<b>Zenapax®</b> daclizumab	PDL Bio Pharma Redwood City, CA	asthma	Phase II (650) 454-1000
zileuton	Critical Therapeutics Lexington, MA	COPD	Phase III (781) 402-5700
		----- acute asthma	Phase II (781) 402-5700
<b>Zmax®</b> azithromycin controlled-release microspheres	Pfizer New York, NY	acute exacerbations of chronic bronchitis	application submitted (860) 732-5156

## MUSCULOSKELETAL DISORDERS

Product Name	Sponsor	Indication	Development Status
aceclofenac	Valeant Pharmaceuticals <i>Aliso Viejo, CA</i>	rheumatic disorders	application submitted (800) 548-5100
<b>Arcalyst™</b> rilonacept	Regeneron Pharmaceuticals <i>Tarrytown, NY</i>	gout	Phase II (914) 345-7400
<b>Arcoxia™</b> etoricoxib	Merck <i>Whitehouse Station, NJ</i>	gout (see also osteoarthritis, pain, rheumatoid arthritis)	Phase III (800) 672-6372
CG-100649	CrystalGenomics <i>Seoul, South Korea</i>	inflammation	Phase I
<b>Chondrogen™</b> mesenchymal stem cell therapy	Osiris Therapeutics <i>Baltimore, MD</i>	repair damaged tissue in the knee and prevent progression of osteoarthritis	Phase I/II (410) 522-5005
<b>Colstat™</b> colchicine	URL Pharma <i>Philadelphia, PA</i>	gout	Phase III completed (215) 697-1900
<b>Puricase®</b> pegloticase <b>(Orphan Drug)</b>	Savient Pharmaceuticals <i>East Brunswick, NJ</i>	severe gout	application submitted (732) 418-9300
RDEA-594	Ardea Biosciences <i>San Diego, CA</i>	gout	Phase I (858) 652-6500
RDEA-806	Ardea Biosciences <i>San Diego, CA</i>	gout	Phase I (858) 652-6500
SAR479746/ MLNM0415 (oral IKK-β inhibitor)	sanofi-aventis <i>Bridgewater, NJ</i> Millennium Pharmaceuticals <i>Cambridge, MA</i>	arthritis	Phase I (800) 633-1610 (800) 390-5663

## OSTEOARTHRITIS

Product Name	Sponsor	Indication	Development Status
462795 (relacatib)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Human Genome Sciences <i>Rockville, MD</i>	osteoarthritis (see also osteoporosis)	Phase I (888) 825-5249
AGG-523	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	osteoarthritis	Phase I (800) 934-5556
<b>Arcoxia™</b> etoricoxib	Merck <i>Whitehouse Station, NJ</i>	osteoarthritis (see also musculoskeletal, pain, rheumatoid arthritis)	application submitted (800) 672-6372
CE-224535	Pfizer <i>New York, NY</i>	osteoarthritis (see also rheumatoid arthritis)	Phase II (860) 732-5156
chondroitin sulfate	Bioiberica <i>Barcelona, Spain</i>	osteoarthritis	Phase III
CRx-102	CombinatoRX <i>Cambridge, MA</i>	osteoarthritis	Phase II (617) 301-7000

## OSTEOARTHRITIS

Product Name	Sponsor	Indication	Development Status
fibroblast growth factor-18 (FGF-18)	EMD Serono <i>Rockland, MA</i>	osteoarthritis	Phase I (800) 283-8088
ibuprofen-PC	PLx Pharma <i>Houston, TX</i>	osteoarthritis	Phase II (713) 842-1249
IDEA-033 (ketoprofen transdermal)	Alparma <i>Bridgewater, NJ</i>	osteoarthritis (see also pain)	Phase III (866) 322-2525
LAS-34475	Almirall-Prodesfarma <i>Barcelona, Spain</i>	osteoarthritis (see also pain)	Phase II/III
naproxcinod	NicOx <i>Warren Township, NJ</i>	osteoarthritis	Phase III (908) 604-1070
PN-400	AstraZeneca <i>Wilmington, DE</i> POZEN <i>Chapel Hill, NC</i>	osteoarthritis (see also rheumatoid arthritis)	Phase III (800) 236-9933 (919) 913-1030
pralnacasan (VX-740)	Vertex Pharmaceuticals <i>Cambridge, MA</i>	osteoarthritis (see also rheumatoid arthritis)	Phase II (617) 444-6777
<b>Prexige</b> <sup>®</sup> lumiracoxib	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	osteoarthritis (see also pain, rheumatoid arthritis)	application submitted (888) 669-6682
SC-84250	Pfizer <i>New York, NY</i>	osteoarthritis	Phase II (860) 732-5156
SMC-021 (oral salmon calcitonin using eligen <sup>®</sup> technology)	Emisphere Technologies <i>Tarrytown, NY</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	osteoarthritis (see also osteoporosis)	Phase III (914) 347-2220 (800) 669-6682
<b>ThermoProfen</b> <sup>™</sup> ketoprofen patch	ZARS Pharma <i>Salt Lake City, UT</i>	osteoarthritis	Phase III (801) 350-0202
<b>Titragesia</b> <sup>™</sup> fentanyl patch	ZARS Pharma <i>Salt Lake City, UT</i>	osteoarthritis (see also pain)	Phase II (801) 350-0202
<b>Vicodin</b> <sup>®</sup> CR hydrocodone/paracetamol controlled-release	Abbott Laboratories <i>Abbott Park, IL</i>	osteoarthritis (see also pain)	application submitted (847) 936-1189
<b>Vimpat</b> <sup>®</sup> lacosamide	Schwarz Pharma <i>Mequon, WI</i>	osteoarthritis (see also epilepsy, pain)	Phase II (800) 558-5114
WAY-195725	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	osteoarthritis (see also rheumatoid arthritis)	Phase I (800) 934-5556

## OSTEOPOROSIS

Product Name	Sponsor	Indication	Development Status
462795 (relacatib)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Human Genome Sciences <i>Rockville, MD</i>	post-menopausal osteoporosis (see also osteoarthritis)	Phase I (888) 825-5249

## OSTEOPOROSIS

Product Name	Sponsor	Indication	Development Status
768974 (parathyroid hormone receptor agonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	osteoporosis	Phase I (888) 825-5249
AC-100	Acologix <i>Hayward, CA</i>	post-menopausal osteoporosis	Phase I (510) 512-7200
ACE-011	Acceleron Pharma <i>Cambridge, MA</i> Celgene <i>Summit, NJ</i>	post-menopausal osteoporosis	Phase I (617) 649-9200 (908) 673-9000
AMG 785	Amgen <i>Thousand Oaks, CA</i>	osteoporosis	Phase I (805) 447-1000
<b>Aprala™</b> bazedixifene conjugated estrogens	Ligand Pharmaceuticals <i>San Diego, CA</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	post-menopausal osteoporosis (prevention)	Phase III (858) 550-7500 (800) 934-5556
<b>Aredia®</b> pamidronic acid	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	corticosteroid-induced osteoporosis (see also pain)	in clinical trials (888) 669-6682
arzoixifene	Eli Lilly <i>Indianapolis, IN</i>	post-menopausal osteoporosis (prevention and treatment)	Phase III (800) 545-5979
ATF936	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	osteoporosis	Phase I completed (888) 669-6682
BA-058	Radius Health <i>Cambridge, MA</i>	osteoporosis	Phase II (617) 551-4700
BAY 39-9624	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	post-menopausal osteoporosis	Phase I (888) 842-2937
<b>Bonviva®</b> ibandronate	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Roche <i>Nutley, NJ</i>	post-menopausal osteoporosis (prevention) (quarterly IV dosing)	Phase III (888) 825-5249 (973) 235-5000
calcitonin oral	Unigene Laboratories <i>Boonton, NJ</i>	post-menopausal osteoporosis	Phase I/II (973) 265-1100
<b>Cenestin®</b> conjugated estrogens oral	Duramed Pharmaceuticals <i>Montvale, NJ</i>	post-menopausal osteoporosis (prevention)	Phase II/III (201) 930-3300
denosumab	Amgen <i>Thousand Oaks, CA</i>	treatment-induced osteoporosis, cancer-related osteoporosis (prevention), post-menopausal osteoporosis (see also rheumatoid arthritis)	Phase III (805) 447-1000
JTT-305	Merck <i>Whitehouse Station, NJ</i>	osteoporosis	Phase II (800) 672-6372
letrozole	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	osteoporosis	Phase III (888) 669-6682

## OSTEOPOROSIS

Product Name	Sponsor	Indication	Development Status
LGD-2941	Ligand Pharmaceuticals <i>San Diego, CA</i>	osteoporosis	Phase I (858) 550-7500
odanacatib (MK-0822)	Merck <i>Whitehouse Station, NJ</i>	post-menopausal osteoporosis	Phase III (800) 672-6372
<b>Ophena™</b> ospemifene	QuatRx Pharmaceuticals <i>Ann Arbor, MI</i>	post-menopausal osteoporosis (prevention and treatment)	Phase II (734) 913-9900
<b>Oporia®</b> lasofoxifene	Ligand Pharmaceuticals <i>San Diego, CA</i> Pfizer <i>New York, NY</i>	post-osteoporosis (prevention and treatment)	application submitted (860) 732-5156
parathyroid hormone oral	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Unigene Laboratories <i>Boonton, NJ</i>	osteoporosis	Phase I (888) 825-5249 (973) 265-1100
<b>Reclast®</b> zoledronic acid	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	osteoporosis (prevention)	Phase III (888) 669-6682
SMC-021 (oral salmon calcitonin using eligen® technology)	Emisphere Technologies <i>Tarrytown, NY</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	post-menopausal osteoporosis (see also osteoarthritis)	Phase III (914) 347-2220 (888) 669-6682
teriparatide intranasal	MDRNA <i>Bothell, WA</i>	osteoporosis	Phase II (425) 908-3600
teriparatide oral	Emisphere Technologies <i>Tarrytown, NY</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	post-menopausal osteoporosis	Phase I (914) 347-2220 (888) 669-6682
teriparatide transdermal	Eli Lilly <i>Indianapolis, IN</i> TransPharma Medical <i>Lod, Israel</i>	osteoporosis	Phase I/II (800) 545-5979
teriparatide transdermal	Zosano Pharma <i>Fremont, CA</i>	osteoporosis	Phase II (510) 745-1200
VEL-0230	Velcura Therapeutics <i>Ann Arbor, MI</i>	osteoporosis (see also rheumatoid arthritis)	Phase I (734) 973-1000
<b>Viviant™</b> bazedoxifene	Ligand Pharmaceuticals <i>San Diego, CA</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	post-menopausal osteoporosis (prevention and treatment)	application submitted (800) 934-5556

## PAIN

Product Name	Sponsor	Indication	Development Status
406381 (dual acting COX-2 inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	acute and chronic pain	Phase III (888) 825-5249

## PAIN

Product Name	Sponsor	Indication	Development Status
681323 (p38 kinase inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	neuropathic pain (see also lung, rheumatoid arthritis)	Phase II (888) 825-5249
842166 (non-cannabinoid CB2 agonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	dental pain, musculoskeletal pain	Phase II (888) 825-5249
ABT-894	Abbott Laboratories <i>Abbott Park, IL</i>	diabetic neuropathies	Phase II (847) 937-6100
<b>Acetavance™</b> paracetamol intravenous	Cadence Pharmaceuticals <i>San Diego, CA</i>	acute pain	Phase III (858) 426-1400
<b>Acurox™</b> oxycodone/niacin	Acura Pharmaceuticals <i>Palantine, IL</i>	pain	Phase III (847) 705-7709
ADL5859	Adolor <i>Exton, PA</i> Pfizer <i>New York, NY</i>	dental pain, diabetic neuropathies, inflammatory pain	Phase II (484) 595-1500 (860) 732-5156
AGN201781	ACADIA Pharmaceuticals <i>San Diego, CA</i> Allergan <i>Irvine, CA</i>	neuropathic pain	Phase II (858) 558-2871 (714) 246-4500
AGN203818	ACADIA Pharmaceuticals <i>San Diego, CA</i> Allergan <i>Irvine, CA</i>	diabetic neuropathies, pain	Phase II (858) 558-2871 (714) 246-4500
ALGRX-4975 <b>(Orphan Drug)</b>	Anesiva <i>South San Francisco, CA</i>	post-operative pain	Phase III (650) 624-9600
		neuropathic pain, pain	Phase II (650) 624-9600
amelior	Cumberland Pharmaceuticals <i>Nashville, TN</i>	post-operative pain	Phase III (666) 423-7259
AMG 379	Amgen <i>Thousand Oaks, CA</i>	pain	Phase I (800) 772-6436
AMG 403	Amgen <i>Thousand Oaks, CA</i>	pain	Phase I (800) 772-6436
apricoxib	Tragara Pharmaceuticals <i>San Diego, CA</i>	inflammatory pain	Phase II (858) 350-6900
ARC-4558	Arcion Therapeutics <i>Baltimore, MD</i>	diabetic neuropathies	Phase II (301) 325-3718
<b>Arcoxia™</b> etoricoxib	Merck <i>Whitehouse Station, NJ</i>	back pain, dental pain (see also musculoskeletal, osteoarthritis, rheumatoid arthritis)	Phase III (800) 672-6372
<b>Aredia®</b> pamidronic acid	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	cancer pain (see also osteoporosis)	Phase III (888) 669-6682

## PAIN

Product Name	Sponsor	Indication	Development Status
ARRY-797	Array BioPharma <i>Boulder, CO</i>	inflammatory pain (see also rheumatoid arthritis)	Phase II (877) 633-2436
AT-3022	Altea Therapeutics <i>Atlanta, GA</i>	pain	Phase I (404) 835-6310
AV411	Avigen <i>Alameda, CA</i>	neuropathic pain	Phase I (510) 748-7150
AVP-923	Avanir Pharmaceuticals <i>San Diego, CA</i>	diabetic neuropathies	Phase III completed (858) 622-5200
AZD1386	AstraZeneca <i>Wilmington, DE</i>	chronic nociceptive pain (see also gastrointestinal)	Phase I (800) 236-9933
AZD1704	AstraZeneca <i>Wilmington, DE</i>	pain	Phase I (800) 236-9933
AZD1940	AstraZeneca <i>Wilmington, DE</i>	neuropathic pain	Phase I (800) 236-9933
AZD2066	AstraZeneca <i>Wilmington, DE</i>	pain (see also gastrointestinal)	Phase I (800) 236-9933
<b>Bema™ LA</b> buprenorphine transmucosal	Biodelivery Sciences <i>Raleigh, NC</i>	pain	Phase I (919) 582-9050
bicifadine	XTL Biopharmaceuticals <i>Valley Cottage, NY</i>	diabetic neuropathies	Phase II (845) 267-0707
bupivacaine	Pacira Pharmaceuticals <i>San Diego, CA</i>	post-operative pain	Phase II (858) 625-2424
buprenorphine transdermal	Mundipharma <i>Cambridge, United Kingdom</i>	pain	Phase III
butorphanol intranasal	Intranasal Therapeutics <i>Lexington, KY</i>	pain	Phase III (859) 252-5080
carisbamate	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	diabetic neuropathies, post-herpetic neuralgia (see also epilepsy, other)	Phase II (800) 817-5286
CDS PM101	pSivida <i>Watertown, MA</i>	post-operative pain	Phase I (617) 926-5000
CEP-28190	Cephalon <i>Frazer, PA</i>	pain	Phase I (610) 344-0200
<b>Chronogesic®</b> sufentanil transdermal	Durect <i>Cupertino, CA</i> Endo Pharmaceuticals <i>Chadds Ford, PA</i>	pain	Phase II (408) 777-1417 (610) 558-9800
CJ 15161	Pfizer <i>New York, NY</i>	back pain, cancer pain	Phase II (860) 732-5156
CNSB001	CNSBio <i>Abbotsford, Australia</i>	neuropathic pain	Phase I/II

## PAIN

Product Name	Sponsor	Indication	Development Status
COL-003	Collegium Pharmaceuticals <i>Cumberland, RI</i>	pain	Phase I (401) 762-2000
<b>CollaRx® Bupivacaine Implant</b>	Innocoll <i>Ashburn, VA</i>	post-operative pain	Phase II
CPL-7075	Cervelo Pharmaceuticals <i>Princeton, NJ</i>	pain	Phase I (888) 450-0111
CR665	Cara Therapeutics <i>Shelton, CT</i>	post-operative pain	Phase II (203) 567-1500
CR845	Cara Therapeutics <i>Shelton, CT</i>	pain	Phase I (203) 567-1500
DD5	Cephalon <i>Frazer, PA</i>	pain	Phase I (610) 344-0200
DPI-125	Mount Cook Biosciences <i>New York, NY</i>	pain	Phase I
dronabinol/ cannabidiol	GW Pharmaceuticals <i>Wiltshire, United Kingdom</i>	cancer pain	Phase III (800) 562-3974
	Otsuka America Pharmaceutical <i>Rockville, MD</i>	neuropathic pain	Phase II (800) 562-3974
duloxetine	Eli Lilly <i>Indianapolis, IN</i>	back pain, musculoskeletal pain	application submitted (800) 545-5979
<b>Dyloject™ injectable diclofenac</b>	Javelin Pharmaceuticals <i>Cambridge, MA</i>	post-operative pain	Phase III (617) 349-4500
<b>Eladur™ bupivacaine transdermal (Orphan Drug)</b>	DURECT <i>Cupertino, CA</i> Alpharma <i>Bridgewater, NJ</i>	post-herpetic neuralgia	Phase II (408) 777-1417 (334) 288-1288
		pain	Phase I (408) 777-1417 (334) 288-1288
<b>Embeda™ morphine extended-release/ naltrexone combination</b>	Alpharma <i>Bridgewater, NJ</i>	pain	application submitted (866) 322-2525
EN3294 (inhaled fentanyl)	Alexza Pharmaceuticals <i>Palo Alto, CA</i> Endo Pharmaceuticals <i>Chadds Ford, PA</i>	acute pain	Phase I (650) 944-7000 (610) 558-9800
fadolmidine	Orion Pharma <i>Espoo, Finland</i>	post-operative pain, pain	Phase II
fentanyl sublingual spray	INSYS Therapeutics <i>Phoenix, AZ</i>	cancer pain	Phase III (602) 910-2617
fentanyl transdermal patch	Lavipharm <i>East Windsor, NJ</i>	cancer pain	Phase III (609) 448-3001

## PAIN

Product Name	Sponsor	Indication	Development Status
<b>Fentora®</b> fentanyl effervescent buccal tablet	Cephalon <i>West Chester, PA</i>	breakthrough pain, neuropathic pain	application submitted (610) 344-0200
<b>Gabapentin GR™</b> gabapentin extended-release	Depomed <i>Menlo Park, CA</i>	post-herpetic neuralgia	Phase III (650) 462-5900
		diabetic neuropathies	Phase II (650) 462-5900
<b>Gabitril®</b> tiagabine	Cephalon <i>Frazer, PA</i>	neuropathic pain (see also sleep)	Phase II (610) 344-0200
glial cell modulator	Solace Pharmaceuticals <i>Boston, MA</i>	pain	Phase I <a href="http://www.solacepharma.com">www.solacepharma.com</a>
GRC-6211	Eli Lilly <i>Indianapolis, IN</i>	dental pain (see also bladder)	Phase II (800) 545-5979
		neuropathic pain	Phase I (800) 545-5979
hydromorphone controlled-release	Neuromed Pharmaceuticals <i>Philadelphia, PA</i>	pain	Phase III (484) 533-6900
hydromorphone intranasal	Intranasal Therapeutics <i>Lexington, KY</i>	moderate to severe acute pain	Phase II (859) 252-5080
hydromorphone transdermal	Altea Therapeutics <i>Tucker, GA</i>	acute and chronic pain	Phase II (678) 495-3100
HZT-501 (ibuprofen/ famotidine)	Horizon Therapeutics <i>Palo Alto, CA</i>	pain	Phase III (650) 324-8700
ICA-105665	Icagen <i>Durham, NC</i>	neuropathic pain (see also epilepsy)	Phase I (919) 941-5206
IDEA-033 (ketoprofen transdermal)	Alpharma <i>Bridgewater, NJ</i>	pain (see also osteoarthritis)	Phase III (866) 322-2525
indantadol	Vernalis Pharmaceuticals <i>Morristown, NJ</i>	neuropathic pain	Phase II (888) 376-2547
IV-adenosine	Xsira Pharmaceuticals <i>Morrisville, NC</i>	post-operative pain	Phase II (919) 248-8000
KD-7040	Kalypsys <i>San Diego, CA</i>	neuropathic pain	Phase II (858) 754-3300
KDS-2000	Kadmus Pharmaceuticals <i>Irvine, CA</i>	post-herpetic neuralgia	Phase II (949) 725-3700
<b>Ketotransdel™</b> transdermal ketoprofen	Transdel Pharmaceuticals <i>La Jolla, CA</i>	acute pain	Phase III (858) 457-5300
KRN5500	DARA Biosciences <i>Raleigh, NC</i>	neuropathic pain	Phase II (919) 872-5578

## PAIN

Product Name	Sponsor	Indication	Development Status
<b>Lamictal®</b> lamotrigine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	neuropathic pain (see also depression)	Phase III (888) 825-5249
LAS-34475	Almirall-Prodesfarma <i>Barcelona, Spain</i>	pain (see also osteoarthritis)	Phase II
<b>LidoPAIN® BP</b> lidocaine transdermal patch	Endo Pharmaceuticals <i>Chadds Ford, PA</i> EpiCept <i>Tarrytown, NY</i>	acute lower back pain	Phase II completed (610) 558-9800 (914) 606-3500
<b>LidoPAIN® SP</b> lidocaine transdermal patch	EpiCept <i>Tarrytown, NY</i>	surgical incision pain	Phase II completed (914) 606-3500
lornoxicam	POZEN <i>Chapel Hill, NC</i>	post-operative pain	Phase I/II (919) 913-1030
LPCN-1029	Lipocine <i>Salt Lake City, UT</i>	pain	Phase I (801) 994-7383
<b>Lyrica®</b> pregabalin	Pfizer <i>New York, NY</i>	post-operative pain (see also sleep)	Phase III (860) 732-5156
M6G	PAION <i>Aachen, Germany</i>	pain	Phase I
MCC-257	Mitsubishi Tanabe Pharma America <i>Warren, NJ</i>	diabetic neuropathies	Phase II (908) 607-1950
mepivacaine controlled-release (APF-112)	A.P. Pharma <i>Redwood City, CA</i>	post-operative pain	Phase II (650) 366-2626
MGX-001	Victory Pharma <i>San Diego, CA</i>	pain	Phase II (858) 720-4500
MK-0686	Merck <i>Whitehouse Station, NJ</i>	post-herpetic neuralgia	Phase II (800) 672-6372
MK-0703	Merck <i>Whitehouse Station, NJ</i>	pain	Phase II (800) 672-6372
MK-0759	Merck <i>Whitehouse Station, NJ</i>	post-herpetic neuralgia	Phase II (800) 672-6372
MK-2295	Merck <i>Whitehouse Station, NJ</i> Neurogen <i>Branford, CT</i>	pain	Phase II (800) 672-6372 (203) 488-8201
morphine intranasal	MDRNA <i>Bothell, WA</i>	cancer pain, dental pain, pain	Phase II (425) 908-3600
morphine oral	Generex Biotechnology <i>Toronto, ON</i>	pain	Phase I (416) 364-2551
morphine oral sustained-release	Xanodyne Pharmaceuticals <i>Newport, KY</i>	pain	Phase III (859) 371-6383
<b>Myocloc®</b> botulinum toxin B	Solstice Neurosciences <i>South San Francisco, CA</i>	pain	in clinical trials (650) 243-4400

## PAIN

Product Name	Sponsor	Indication	Development Status
<b>Nasalfent®</b> fentanyl intranasal	Archimedes Pharma <i>Reading, United Kingdom</i>	cancer pain	Phase III
NGX426	TorreyPines Therapeutics <i>La Jolla, CA</i>	neuropathic pain	Phase I (858) 623-5665
NGX-1998 (capsaicin topical)	NeurogesX <i>San Mateo, CA</i>	pain	Phase I (650) 358-3300
NGX-4010	NeurogesX <i>San Carlos, CA</i>	post-herpetic neuralgia	application submitted (650) 508-2116
		diabetic neuropathies	Phase II (650) 508-2116
NP-1 (amitriptyline/ ketamine)	EpiCept <i>Tarrytown, NY</i>	neuropathic pain	Phase III (914) 606-3500
NP2	Diamyd Medical <i>Pittsburgh, PA</i>	cancer pain	Phase I (412) 770-1310
NP-2 (ketamine/ butamben topical)	Epicept <i>Tarrytown, NY</i>	neuropathic pain	Phase I/II (914) 606-3500
OMS103HP	Omeros <i>Seattle, WA</i>	post-operative pain	Phase III (206) 676-5000
OMS201	Omeros <i>Seattle, WA</i>	surgically-induced pain	Phase I (206) 676-5000
<b>Onsolis™</b> fentanyl buccal	Biodelivery Sciences <i>Raleigh, NC</i> Meda Pharmaceuticals <i>Somerset, NJ</i>	cancer pain	application submitted (919) 582-9050
opioid analgesic	Zogenix <i>San Diego, CA</i>	pain	Phase II (858) 259-1165
<b>OxyNal™</b> oxycodone/ naltrexone	Elite Pharmaceuticals <i>Northvale, NJ</i>	pain	Phase II (201) 750-2646
<b>OxyQD™</b> oxycodone once-daily	Elite Pharmaceuticals <i>Northvale, NJ</i>	pain	Phase I (201) 750-2646
<b>Oxytrex™</b> oxycodone and low-dose naltrexone	Pain Therapeutics <i>San Mateo, CA</i>	musculoskeletal pain	Phase III (650) 624-8200
parecoxib	Pfizer <i>New York, NY</i>	pain	application submitted (860) 732-5156
<b>Pennsaid®</b> diclofenac transdermal	Nuvo Research <i>Mississauga, ON</i>	musculoskeletal pain associated with osteoarthritis	application submitted (905) 673-6980

## PAIN

Product Name	Sponsor	Indication	Development Status
perampanel (E2007)	Eisai Medical Research <i>Ridgefield Park, NJ</i>	neuropathic pain (see also epilepsy)	Phase II (888) 422-4743
PF-2393296	Pfizer <i>New York, NY</i>	pain	Phase I (860) 732-5156
PF-3557156	Pfizer <i>New York, NY</i>	pain	Phase I (860) 732-5156
PF-3864086	Pfizer <i>New York, NY</i>	pain	Phase I (860) 732-5156
PF-4136309	Pfizer <i>New York, NY</i>	pain	Phase II (860) 732-5156
PF-4191834	Pfizer <i>New York, NY</i>	pain (see also lung)	Phase I (860) 732-5156
PF-4383119 (tanezumab)	Pfizer <i>New York, NY</i>	back pain, cancer pain, musculoskeletal pain, neuralgia	Phase II (860) 732-5156
PF-4457845	Pfizer <i>New York, NY</i>	pain	Phase I (860) 732-5156
PF-4480682	Pfizer <i>New York, NY</i>	neuropathic pain	Phase II (860) 732-5156
PF-4856880	Pfizer <i>New York, NY</i>	pain	Phase II (860) 732-5156
PF-4856881	Pfizer <i>New York, NY</i>	pain	Phase I (860) 732-5156
PH-797804	Pfizer <i>New York, NY</i>	neuropathic pain (see also lung, rheumatoid arthritis)	Phase II (860) 732-5156
PL2100	PLx Pharma <i>Houston, TX</i>	pain	Phase I (713) 842-1249
PLX5568	Plexxikon <i>Berkeley, CA</i>	pain	Phase I (510) 647-4000
PMI-150 (intranasal ketamine)	Javelin Pharmaceuticals <i>Cambridge, MA</i>	acute pain, cancer pain	Phase III (617) 349-4500
<b>Posidur™</b> bupivacaine controlled-release	DURECT <i>Cupertino, CA</i>	post-operative pain	Phase II (408) 777-1417
<b>Prexige®</b> lumiracoxib	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	pain (see also osteoarthritis, rheumatoid arthritis)	Phase III (888) 669-6682
<b>Pristiq™</b> desvenlafaxine	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	neuropathic pain	Phase III (800) 934-5556
PRO-571 (diclofenac rapid-release)	Kowa Pharmaceuticals America <i>Montgomery, AL</i>	pain	Phase I (334) 288-1288
<b>Probuphine®</b> buprenorphine implant (slow-release)	Titan Pharmaceuticals <i>South San Francisco, CA</i>	pain	Phase I (650) 244-4990

## PAIN

Product Name	Sponsor	Indication	Development Status
PSD-597	Plethora Solutions <i>London, England</i>	perioperative pain	Phase II
PTI-202	King Pharmaceuticals <i>Bristol, TN</i> Pain Therapeutics <i>San Mateo, CA</i>	pain	Phase I (800) 776-3637 (650) 624-8200
PW4142 (nalbuphine extended-release)	Penwest Pharmaceuticals <i>Danbury, CT</i>	pain	Phase II (203) 796-3700
Q8003IR (morphine/ oxycodone immediate-release)	QRxPharma <i>North Sydney, Australia</i>	moderate to severe post-operative pain	Phase III
QR-333	Quigley Pharma <i>Doylestown, PA</i>	diabetic neuropathies	Phase II (267) 880-1100
QSC-001	Questcor Pharmaceuticals <i>Union City, PA</i>	pain	Phase I (510) 400-0700
R1646	Roche <i>Nutley, NJ</i>	pain (see also bladder)	Phase I (973) 235-5000
R331333 (immediate-release)	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	pain, post-operative pain	Phase III (800) 817-5286
R331333 PR (controlled-release)	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	back pain, diabetic neuropathies, pain	Phase III (800) 817-5286
radiprodil	Forest Laboratories <i>New York, NY</i>	pain	Phase II (800) 947-5227
ranirestat (AS-3201)	Eisai Medical Research <i>Ridgefield Park, NJ</i>	diabetic neuropathies	application submitted (888) 422-4743
<b>Rapinyl™</b> fentanyl sublingual	Orexo <i>Uppsala, Sweden</i>	breakthrough cancer pain	Phase III
<b>Remoxy™</b> oxycodone	DURECT <i>Cupertino, CA</i> King Pharmaceuticals <i>Bristol, TN</i> Pain Therapeutics <i>San Mateo, CA</i>	pain	application submitted (800) 776-3637 (650) 624-8200
retigabine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Valeant Pharmaceuticals <i>Aliso Viejo, CA</i>	post-herpetic neuralgia (see also epilepsy)	Phase II (888) 825-5249 (800) 548-5100
ROX-888	ROXRO Pharma <i>Menlo Park, CA</i>	post-operative pain	Phase III (650) 322-4554

## PAIN

Product Name	Sponsor	Indication	Development Status
RPI-70	ReceptoPharm <i>Plantation, FL</i>	pain	Phase I (954) 321-8988
<b>Rylomine™</b> intranasal morphine	Javelin Pharmaceuticals <i>Cambridge, MA</i>	post-operative pain	Phase III (617) 349-4500
SAB-378	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	pain	Phase II (888) 669-6682
SB-509	Sangamo BioSciences <i>Richmond, CA</i>	diabetic neuropathies	Phase II (510) 970-6000
SCP-1	St. Charles Pharmaceuticals <i>New Orleans, LA</i>	pain	Phase I (775) 626-0534
SEP-228425	Sepracor <i>Marlborough, MA</i>	pain (see also depression)	Phase I (508) 481-6700
<b>Solzira™</b> gabapentin enacarbil	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> XenoPort <i>Santa Clara, CA</i>	diabetic neuropathies, neuropathic pain, post-herpetic neuralgia (see also sleep)	Phase II (888) 825-5249
SRSS-001	Sosei R&D <i>Tokyo, Japan</i>	cancer pain	Phase I
SSR150106 (cytokine/ chemokine inhibitor)	sanofi-aventis <i>Bridgewater, NJ</i>	pain (see also rheumatoid arthritis)	Phase II (800) 633-1610
SSR180575 (PBR ligand)	sanofi-aventis <i>Bridgewater, NJ</i>	diabetic polyneuropathies	Phase II (800) 633-1610
SYN-116	Roche <i>Nutley, NJ</i> Synosia Therapeutics <i>South San Francisco, CA</i>	pain	Phase I (973) 235-5000 (650) 244-4850
TAK-428	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	diabetic neuropathies	Phase II (224) 554-6500
TAK-583	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	diabetic neuropathies, post-herpetic neuralgia	Phase II (224) 554-6500
<b>TamoGel™</b> afimoxifene	ASCEND Therapeutics <i>Herndon, VA</i>	breast pain	Phase II (703) 471-4744
TC-6499	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Targacept <i>Winston-Salem, NC</i>	neuropathic pain	Phase I (888) 825-5249 (336) 480-2100
<b>Titragesia™</b> fentanyl patch	ZARS Pharma <i>Salt Lake City, UT</i>	cancer pain (see also osteoarthritis)	Phase III (801) 350-0202
<b>Topamax®</b> topiramate	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	diabetic neuropathies	Phase III (800) 817-5286

## PAIN

Product Name	Sponsor	Indication	Development Status
TQ-1011 (ketoprofen intravenous)	TheraQuest Biosciences <i>Blue Bell, PA</i>	post-operative pain	Phase II (610) 272-2071
TQ-1017 (tramadol extended-release)	Theraquest Biosciences <i>Blue Bell, PA</i>	neuropathic pain	Phase I (610) 272-2071
tramadol CR (controlled-release)	LaboPharm <i>Laval, QC</i> Purdue Pharma <i>Stamford, CT</i>	pain	application submitted (888) 686-1017 (203) 588-8000
tramadol ER (extended-release)	Cipher Pharmaceuticals <i>Mississauga, ON</i>	pain	application submitted (905) 602-5840
tramadol/ paracetamol controlled-release	LaboPharm <i>Laval, QC</i>	pain	Phase III (888) 686-1017
TRPV1 antagonist	Pfizer <i>New York, NY</i>	pain (see also bladder)	Phase I (860) 732-5156
URG301	Urigen Pharmaceuticals <i>Burlingame, CA</i>	pain (see also bladder)	Phase I (650) 259-0239
<b>Vicodin® CR</b> acetaminophen/ hydrocodone	Abbott Laboratories <i>Abbott Park, IL</i>	back pain, post-operative pain (see also osteoarthritis)	application submitted (847) 937-6100
<b>Vimpat®</b> lacosamide	Schwarz Pharma <i>Mequon, WI</i>	diabetic neuropathic pain (see also epilepsy, osteoarthritis)	application submitted (800) 558-5114
WAY-126090 (perzinfotel)	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	neuropathic pain, pain	Phase II (800) 934-5566
<b>Xibrom™ QD</b> bromfenac once-daily	Ista Pharmaceuticals <i>Irvine, CA</i>	ocular pain	Phase III (949) 788-6000
<b>Zipor®</b> diclofenac	Xanodyne Pharmaceuticals <i>Newport, KY</i>	pain	application submitted (877) 926-6396
zucapsaicin	OPKA Health <i>Miami, FL</i>	osteoarthritis pain	Phase III (305) 575-6000

## PARKINSON'S DISEASE

Product Name	Sponsor	Indication	Development Status
ACP-103 (pimavanserin)	ACADIA Pharmaceuticals <i>San Diego, CA</i>	Parkinson's disease-associated psychosis	Phase III (858) 558-2871
		treatment-induced dysfunctions in Parkinson's disease	Phase II (858) 558-2871
<b>Altropane®</b> diagnostic imaging agent	Alseres Pharmaceuticals <i>Hopkinton, MA</i>	imaging agent for the diagnosis of early Parkinsonism	Phase III (508) 497-2360

## PARKINSON'S DISEASE

Product Name	Sponsor	Indication	Development Status
aplindore	Neurogen <i>Branford, CT</i>	Parkinson's disease (see also sleep)	Phase II (203) 488-8201
apomorphine transdermal patch	Altea Therapeutics <i>Atlanta, GA</i>	Parkinson's disease	Phase I (404) 835-6310
AV-201 gene therapy	Genzyme <i>Cambridge, MA</i>	Parkinson's disease	Phase I/II (617) 252-7500
AZD3241	AstraZeneca <i>Wilmington, DE</i>	Parkinson's disease	Phase I (800) 236-9933
CERE-120	Ceregene <i>San Diego, CA</i> Genzyme <i>Cambridge, MA</i>	Parkinson's disease	Phase II (858) 458-8800 (617) 252-7500
DAR-100	DarPharma <i>Chapel Hill, NC</i>	Parkinson's disease (see also Alzheimer's)	Phase I/II (919) 403-4348
<b>Duodopa®</b> levodopa/ carbidopa intraduodenal <b>(Orphan Drug)</b>	Solvay Pharmaceuticals <i>Marietta, GA</i>	Parkinson's disease (late-stage disease)	Phase III (770) 578-9000
fipamezole	Juventia Pharma <i>Turku, Finland</i> Santhera Pharmaceuticals <i>Charlestown, MA</i>	Parkinson's disease	Phase II www.santhera.com
IPX054 (levodopa/ carbidopa)	IMPAX Laboratories <i>Hayward, CA</i>	Parkinson's disease	Phase I (510) 476-2000
<b>Kinampa™</b> talampanel	IVAX <i>Miami, FL</i>	dyskinesia in Parkinson's disease	Phase II (305) 575-6000
KW-6002 (istradefylline)	Kyowa Pharmaceutical <i>Princeton, NJ</i>	Parkinson's disease (adjunctive treatment)	application submitted (609) 919-1100
MK-0657	Merck <i>Whitehouse Station, NJ</i>	Parkinson's disease	Phase I (800) 672-6372
<b>Nectiv™</b> traxoprodil	Pfizer <i>New York, NY</i>	Parkinson's disease (see also depression)	in clinical trials (860) 732-5156
<b>NEOtime™</b> creatine monohydrate	Avicena <i>Palo Alto, CA</i>	Parkinson's disease	Phase III (415) 397-2880
<b>Neupro®</b> rotigotine transdermal	Schwarz Pharma <i>Mequon, WI</i>	Parkinson's disease (adjunctive treatment, late-stage disease) (see also sleep)	application submitted (800) 558-5114
NLX-P101	Neurologix <i>Fort Lee, NJ</i>	Parkinson's disease	Phase II (201) 592-6451
pardoprunox (SLV 308)	Solvay Pharmaceuticals <i>Marietta, GA</i>	Parkinson's disease (see also depression)	Phase III (770) 578-9000

## PARKINSON'S DISEASE

Product Name	Sponsor	Indication	Development Status
pramipexole extended-release	Boehringer-Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	Parkinson's disease	Phase III (800) 243-0127
preladenant	Schering-Plough <i>Kenilworth, NJ</i>	Parkinson's disease	Phase II (908) 298-4000
ropinirole oral spray	NovaDel Pharma <i>Flemington, NJ</i>	Parkinson's disease	Phase I (908) 782-3431
safinamide	EMD Serono <i>Rockland, MA</i>	Parkinson's disease (see also Alzheimer's, sleep)	Phase III (800) 283-8088
SCH-412348 (adenosine 2a receptor antagonist)	Schering-Plough <i>Kenilworth, NJ</i>	Parkinson's disease	Phase II (908) 298-4000
SRx-501 (levodopa/carbidopa extended-release)	Spherics <i>Mansfield, MA</i>	Parkinson's disease	Phase I completed (866) 862-4383
<b>Stalevo</b> <sup>®</sup> entacapone/levodopa/carbidopa combination	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	Parkinson's disease (early-stage disease)	application submitted (888) 669-6682
SYN-115	Roche <i>Nutley, NJ</i> Synosia Therapeutics <i>South San Francisco, CA</i>	Parkinson's disease	Phase I (973) 238-5000 (650) 244-4850
SYN-118 (nitisinone)	Synosia Therapeutics <i>South San Francisco, CA</i>	Parkinson's disease	Phase I (650) 244-4850
ubidecarenone	Enzymatic Therapy <i>Green Bay, WI</i>	Parkinson's disease	Phase II/III (800) 783-2286
V1512	Vernalis <i>Winnersh, United Kingdom</i>	Parkinson's disease	Phase II www.vernalis.com
V2006	Biogen Idec <i>Cambridge, MA</i> Vernalis <i>Winnersh, United Kingdom</i>	Parkinson's disease	Phase II (617) 679-2000 www.vernalis.com
XP21279	XenoPort <i>Santa Clara, CA</i>	Parkinson's disease	Phase I (408) 616-7200

## PROSTATE DISEASE

Product Name	Sponsor	Indication	Development Status
<b>Andrin</b> <sup>™</sup> androgen replacement therapy	ASCEND Therapeutics <i>Herndon, VA</i>	hypogonadism	Phase II (703) 471-4744
		benign prostatic hyperplasia (BPH)	Phase I/II (703) 471-4744

## PROSTATE DISEASE

Product Name	Sponsor	Indication	Development Status
<b>Botox</b> <sup>®</sup> botulinum toxin A	Allergan <i>Irvine, CA</i>	BPH (see also bladder)	Phase II (800) 433-8871
cetorelix	Aeterna Zentaris <i>Warren, NJ</i>	BPH	Phase III (908) 626-5428
dutasteride/ tamsulosin combination	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	BPH	Phase III (888) 825-5249
elagolix (NBI-56418)	Neurocrine Biosciences <i>San Diego, CA</i>	BPH	Phase I (858) 617-7600
lemuteporfin	QLT USA <i>Fort Collins, CO</i>	BPH	Phase II (800) 663-5486
<b>Litx</b> <sup>™</sup> talaporfin	Light Sciences Oncology <i>Bellevue, WA</i>	BPH	Phase I/II (425) 957-8900
NBI-42902	Neurocrine Biosciences <i>San Diego, CA</i>	BPH	Phase I (858) 617-7600
NX-1207	Nymox Pharmaceutical <i>Hasbrouck Heights, NJ</i>	BPH	Phase III (800) 936-9669
ozarelix	Aeterna Zentaris <i>Warren, NJ</i>	BPH	Phase II completed (908) 626-5428
solifenacin/ tamsulosin combination	Astellas Pharma US <i>Deerfield, IL</i>	BPH (see also bladder)	Phase II (800) 477-6472
tadalafil	Eli Lilly <i>Indianapolis, IN</i> ICOS <i>Bothell, WA</i>	BPH	Phase II (800) 545-5979 (877) 285-4559
UK-369003	Pfizer <i>New York, NY</i>	BPH (see also bladder)	Phase II (860) 732-5156

## RHEUMATOID ARTHRITIS

Product Name	Sponsor	Indication	Development Status
274150 (selective iNOS inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	rheumatoid arthritis	Phase II (888) 825-5249
315234 (mAb)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	rheumatoid arthritis	Phase I (888) 825-5249
681323 (p38 kinase inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	rheumatoid arthritis (see also lung, pain)	Phase II (888) 825-5249
856553 (p38 MAP kinase inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	rheumatoid arthritis (see also depression, lung)	Phase II (888) 825-5249
1827771 (interleukin 1 inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	rheumatoid arthritis	Phase I (888) 825-5249

## RHEUMATOID ARTHRITIS

Product Name	Sponsor	Indication	Development Status
<b>Actemra®</b> tocilizumab	Chugai Pharma USA <i>Bedminster, NJ</i>	rheumatoid arthritis	application submitted (908) 947-2700
AIN457	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	rheumatoid arthritis	Phase I (888) 669-6682
AME-527	Applied Molecular Evolution <i>San Diego, CA</i>	rheumatoid arthritis	Phase I/II (858) 597-4990
AMG 108	Amgen <i>Thousand Oaks, CA</i>	rheumatoid arthritis (see also diabetes)	Phase II (800) 772-6436
AMG 827	Amgen <i>Thousand Oaks, CA</i>	rheumatoid arthritis	Phase I (800) 772-6436
anti-C5aR mAb	Novo Nordisk <i>Princeton, NJ</i>	rheumatoid arthritis	Phase I (609) 987-5800
apilimod	Synta Pharmaceuticals <i>Lexington, MA</i>	rheumatoid arthritis (see also gastrointestinal)	Phase II (781) 274-8200
apratostat	Amgen <i>Thousand Oaks, CA</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	rheumatoid arthritis	Phase II (800) 772-6436 (800) 934-5556
<b>Arcoxia™</b> etoricoxib	Merck <i>Whitehouse Station, NJ</i>	rheumatoid arthritis (see also musculoskeletal, osteoarthritis, pain)	Phase III (800) 672-6372
ARRY-162	Array BioPharma <i>Boulder, CO</i>	rheumatoid arthritis	Phase II (303) 381-6600
ARRY-797	Array BioPharma <i>Boulder, CO</i>	rheumatoid arthritis (see also pain)	Phase II (303) 381-6600
ASK-8007	Astallas Pharma US <i>Deerfield, IL</i>	rheumatoid arthritis	Phase I/II (800) 727-7003
AZD5672	AstraZeneca <i>Wilmington, DE</i>	rheumatoid arthritis	Phase II (800) 236-9933
AZD8566	AstraZeneca <i>Wilmington, DE</i>	rheumatoid arthritis	Phase I (800) 236-9933
AZD9056	AstraZeneca <i>Wilmington, DE</i>	rheumatoid arthritis	Phase II (800) 236-9933
BIIB023	Biogen Idec <i>Cambridge, MA</i>	rheumatoid arthritis	Phase I (617) 679-2000
briobacept (BR3-Fc)	Biogen Idec <i>Cambridge, MA</i> Genentech <i>South San Francisco, CA</i>	rheumatoid arthritis	Phase II (617) 679-2000 (650) 225-1000
CAM 3001	MedImmune <i>Gaithersburg, MD</i>	rheumatoid arthritis	Phase I (301) 298-0000
canakinumab	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	early-stage rheumatoid arthritis (see also eye, diabetes, lung)	Phase II/III (888) 669-6682
		rheumatoid arthritis	Phase II (888) 669-6682

## RHEUMATOID ARTHRITIS

Product Name	Sponsor	Indication	Development Status
CCX-354	ChemoCentryx Mountain View, CA GlaxoSmithKline Rsch. Triangle Park, NC	rheumatoid arthritis	Phase I (650) 210-2900 (888) 825-5249
CE-224535	Pfizer New York, NY	rheumatoid arthritis (see also osteoarthritis)	Phase II/III (860) 732-5156
<b>CellCept®</b> mycophenolate mofetil	Aspreva Pharmaceuticals Basking Ridge, NJ	rheumatoid arthritis	Phase III (908) 212-1020
CF-101	Can-Fite BioPharma Petah-Tikva, Israel	rheumatoid arthritis	Phase II www.canfite.com
CH-1504	Chelsea Therapeutics Charlotte, NC	rheumatoid arthritis (see also skin)	Phase II (704) 341-1516
<b>Cimzia™</b> certolizumab pegol	UCB Smyrna, GA	rheumatoid arthritis	application submitted (770) 970-7500
CNTO-136	Centocor Horsham, PA	rheumatoid arthritis	Phase II (610) 651-6000
controlled-release prednisone	Nitec Pharma Reinach, Switzerland SkyePharma Cambridge, MA	rheumatoid arthritis	Phase III (617) 401-3618
CP-195543	Pfizer New York, NY	rheumatoid arthritis	Phase II (860) 732-5156
CP-481715	Pfizer New York, NY	rheumatoid arthritis	Phase I (860) 732-5156
CP-690550	Pfizer New York, NY	rheumatoid arthritis (see also gastrointestinal, skin)	Phase II (860) 732-5156
denosumab	Amgen Thousand Oaks, CA	rheumatoid arthritis (see also osteoporosis)	Phase II (800) 772-6436
doramapimod (BIRB796)	Boehringer-Ingelheim Pharmaceuticals Ridgefield, CT	rheumatoid arthritis (see also gastrointestinal, skin)	Phase II (800) 243-0127
fostamatinib	Rigel Pharmaceuticals South San Francisco, CA	rheumatoid arthritis	Phase II (650) 624-1100
golimumab	Centocor Horsham, PA	rheumatoid arthritis (IV formulation) (see also gastrointestinal, skin)	application submitted (610) 651-6000
		rheumatoid arthritis (subcutaneous formulation)	Phase III (610) 651-6000
HE-3286	Hollis-Eden Pharmaceuticals San Diego, CA	rheumatoid arthritis (see also diabetes, gastrointestinal)	Phase I/II (858) 587-9333
ILV-094	Wyeth Pharmaceuticals Collegeville, PA	rheumatoid arthritis	Phase I (800) 934-5556

## RHEUMATOID ARTHRITIS

Product Name	Sponsor	Indication	Development Status
INCB-3284	Incyte <i>Wilmington, DE</i> Pfizer <i>New York, NY</i>	rheumatoid arthritis	Phase II (302) 498-6700 (860) 732-5156
INCB-18424	Incyte <i>Wilmington, DE</i>	rheumatoid arthritis (see also skin)	Phase II (302) 498-6700
INCB-28050	Incyte <i>Wilmington, DE</i>	rheumatoid arthritis	Phase I (302) 498-6700
interleukin-1 beta antibody	Eli Lilly <i>Indianapolis, IN</i>	rheumatoid arthritis	Phase II (800) 545-5979
KB200	KaloBios Pharmaceuticals <i>South San Francisco, CA</i>	rheumatoid arthritis (see also lung)	Phase I/II (650) 243-3100
LX2931	Lexicon Pharmaceuticals <i>The Woodlands, TX</i>	rheumatoid arthritis	Phase I (281) 863-3000
LY-2127399	Eli Lilly <i>Indianapolis, IN</i>	rheumatoid arthritis	Phase II (800) 545-5979
<b>LymphoStat-B®</b> belimumab	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Human Genome Sciences <i>Rockville, MD</i>	rheumatoid arthritis	Phase II completed (888) 825-5249 (301) 314-4400
MDX-1100	Medarex <i>Princeton, NJ</i>	rheumatoid arthritis (see also gastrointestinal)	Phase II (609) 430-2880
MDX-1342	Medarex <i>Princeton, NJ</i>	rheumatoid arthritis	Phase I (609) 430-2880
MK-0812	Merck <i>Whitehouse Station, NJ</i>	rheumatoid arthritis	Phase II (800) 672-6372
MM-093	Merrimack Pharmaceuticals <i>Cambridge, MA</i>	rheumatoid arthritis (see also skin)	Phase II (617) 441-1000
<b>Neumega®</b> oprelvekin	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	rheumatoid arthritis (see also gastrointestinal)	Phase II (800) 934-5556
<b>Nipent®</b> pentostatin	Hospira <i>Lake Forest, IL</i>	rheumatoid arthritis	Phase II (224) 212-2000
ocrelizumab	Biogen Idec <i>Cambridge, MA</i> Genentech <i>South San Francisco, CA</i>	rheumatoid arthritis	Phase III (617) 679-2000 (650) 225-1000
ofatumumab	Genmab <i>Princeton, NJ</i> GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	rheumatoid arthritis (intravenous) ----- rheumatoid arthritis (subcutaneous)	Phase III (888) 825-5249 ----- Phase I/II (888) 825-5249
oral dnaJP1	Adeona Pharmaceuticals <i>Ann Arbor, MI</i>	rheumatoid arthritis	Phase II (734) 332-7800
oral human gammaglobulin	Latona Life Sciences <i>Phoenix, AZ</i>	rheumatoid arthritis	Phase II (480) 254-8530

## RHEUMATOID ARTHRITIS

Product Name	Sponsor	Indication	Development Status
p38 kinase inhibitor	Bristol-Myers Squibb <i>Princeton, NJ</i>	rheumatoid arthritis	in clinical trials (212) 546-4000
paclitaxel	Angiotech Pharmaceuticals <i>Vancouver, BC</i>	rheumatoid arthritis (see also lung, skin)	Phase II (604) 221-7676
<b>Panzem®</b> 2-methoxyestradiol	EntreMed <i>Rockville, MD</i>	rheumatoid arthritis	Phase I (240) 864-2600
PD-360324	Pfizer <i>New York, NY</i>	rheumatoid arthritis	Phase I (860) 732-5156
PF-251802	Pfizer <i>New York, NY</i>	rheumatoid arthritis	Phase I (860) 732-5156
PF-4171327	Pfizer <i>New York, NY</i>	rheumatoid arthritis	Phase I (860) 732-5156
PH-797804	Pfizer <i>New York, NY</i>	rheumatoid arthritis (see also lung, pain)	Phase II (860) 732-5156
PLA-695 (giripladib)	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	rheumatoid arthritis	Phase I (800) 934-5556
PMI-001	Phytomedics <i>Jamesburg, NJ</i>	rheumatoid arthritis	Phase II (609) 655-0715
PN-400	AstraZeneca <i>Wilmington, DE</i> POZEN <i>Chapel Hill, NC</i>	rheumatoid arthritis (see also osteoarthritis)	Phase III (800) 236-9933 (919) 913-1030
pralnacasan (VX-740)	Vertex Pharmaceuticals <i>Cambridge, MA</i>	rheumatoid arthritis (see also osteoarthritis)	Phase II (617) 444-6777
<b>Prexige®</b> lumiracoxib	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	rheumatoid arthritis (see also osteoarthritis, pain)	Phase III (888) 669-6682
PRTX-100	Protalex <i>New Hope, PA</i>	rheumatoid arthritis	Phase I (215) 862-9720
R348	Rigel Pharmaceuticals <i>South San Francisco, CA</i>	rheumatoid arthritis (see also skin)	Phase II (650) 624-1100
R1295	Roche <i>Nutley, NJ</i>	rheumatoid arthritis	Phase I (973) 235-5000
RWJ-445380	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	rheumatoid arthritis (see also skin)	Phase II (800) 817-5286
SAR153191 (anti-IL-6R mAb)	Regeneron Pharmaceuticals <i>Tarrytown, NY</i> sanofi-aventis <i>Bridgewater, NJ</i>	rheumatoid arthritis	Phase I (800) 633-1610
SBI-087	Trubion Pharmaceuticals <i>Seattle, WA</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	rheumatoid arthritis	Phase I (206) 838-0500 (800) 934-5556
SCIO-469 (talmapimod)	Scios <i>Mountain View, CA</i>	rheumatoid arthritis	Phase II (650) 564-5000

## RHEUMATOID ARTHRITIS

Product Name	Sponsor	Indication	Development Status
SSR150106 (cytokine/ chemokine inhibitor)	sanofi-aventis <i>Bridgewater, NJ</i>	rheumatoid arthritis (see also pain)	Phase II (800) 633-1610
TACI-Ig (atacicept)	EMD Serono <i>Rockland, MA</i>	rheumatoid arthritis (second-line therapy)	Phase II (800) 283-8088
TAK-783	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	rheumatoid arthritis	Phase II (224) 554-6500
tgAAC 94	Targeted Genetics <i>Seattle, WA</i>	rheumatoid arthritis	Phase I/II (206) 623-7612
TRU-015	Trubion Pharmaceuticals <i>Seattle, WA</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	rheumatoid arthritis	Phase II (206) 838-0500 (800) 934-5556
VEL-0230	Velcura Therapeutics <i>Ann Arbor, MI</i>	rheumatoid arthritis (see also osteoporosis)	Phase I (734) 973-1000
VGX-1027	VGX Pharmaceuticals <i>Blue Bell, PA</i>	rheumatoid arthritis (see also diabetes)	Phase I (267) 440-4200
WAY-195725	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	rheumatoid arthritis (see also osteoarthritis)	Phase I (800) 934-5556

## SEPSIS

Product Name	Sponsor	Indication	Development Status
AZD9773	AstraZeneca <i>Wilmington, DE</i>	septic shock	Phase II (800) 236-9933
eritoran tetrasodium (E5564)	Eisai Medical Research <i>Ridgefield Park, NJ</i>	severe sepsis	Phase III (888) 422-4743
NOX-100	Medinox <i>Carlsbad, CA</i>	septic shock	Phase II (760) 603-8989
PHP	Curacyte <i>Munich, Germany</i>	septic shock	Phase III
PMX-622	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	septic shock	Phase II (888) 669-6682
resatorvid (TAK-242)	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	septic shock	Phase III (224) 554-6500
<b>Segard™</b> afelimomab	Abbott Laboratories <i>Abbott Park, IL</i>	sepsis, septic shock	Phase III (847) 938-0000
talactoferrin alfa	Agennix <i>Houston, TX</i>	sepsis	Phase II (713) 552-1091

## SEXUAL DYSFUNCTION

Product Name	Sponsor	Indication	Development Status
<b>Alista™</b> alprostadil topical	VIVUS <i>Mountain View, CA</i>	female sexual arousal disorder	Phase II (650) 934-5200
<b>Andrin™</b> androgen replacement therapy	ASCEND Therapeutics <i>Herndon, VA</i>	hypogonadism (see also prostate)	Phase II (703) 471-4744
<b>Androxal™</b> enclomifene	Repros Therapeutics <i>The Woodlands, TX</i>	hypogonadism	Phase III (281) 719-3400
avanafil	VIVUS <i>Mountain View, CA</i>	erectile dysfunction	Phase II (650) 934-5200
aviptadil/ phentolamine (vasopotin)	Plethora Solutions <i>London, England</i>	erectile dysfunction	Phase III
CP-866087	Pfizer <i>New York, NY</i>	female sexual dysfunction	Phase II (860) 732-5156
dasantafil	Schering-Plough <i>Kenilworth, NJ</i>	erectile dysfunction	Phase II (908) 298-4000
dutasteride/ testosterone combination	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	hypogonadism	Phase I (888) 825-5249
eF-Ment	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	hypogonadism	Phase I (888) 842-2937
flibanserin	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	female sexual dysfunction	Phase III (203) 798-9988
<b>Fortigel™</b> testosterone gel 2%	ProStrakan USA <i>Bedminster, NJ</i>	male hormone replacement therapy, hypogonadism	Phase III (908) 234-1096
hMaxi-K gene therapy	Ion Channel Innovations <i>New York, NY</i>	erectile dysfunction (see also bladder)	Phase I (212) 639-1561
<b>Nasobol®</b> testosterone intranasal	Mattern Pharmaceuticals <i>Stans, Switzerland</i>	hypogonadism	Phase II
<b>Nebido®</b> testosterone undecanoate depot injection	Indevus Pharmaceuticals <i>Lexington, MA</i>	hypogonadism	application submitted (781) 861-8444
<b>Opterone™</b> SEPA-enhanced testosterone	MacroChem <i>Lexington, MA</i>	testosterone deficiency	Phase I (781) 862-4003
<b>Oritex™</b> testosterone oral	Clarus Therapeutics <i>Northbrook, IL</i>	hypogonadism	Phase II (847) 562-4300
SLX 2101	Surface Logix <i>Brighton, MA</i>	erectile dysfunction	Phase II completed (617) 746-8500
testosterone glucoside	ProStrakan USA <i>Bedminster, NJ</i>	hypogonadism	Phase II (908) 234-1096

## SEXUAL DYSFUNCTION

Product Name	Sponsor	Indication	Development Status
<b>Testosterone MD-Lotion™</b> testosterone lotion	Acrux <i>West Melbourne, Australia</i>	hypogonadism	Phase III
testosterone topical	Novavax <i>Rockville, MD</i>	female sexual dysfunction	Phase II (240) 268-2000
testosterone transdermal	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	hypogonadism	Phase I (888) 842-2937
testosterone transdermal	Pierre Fabre Pharmaceuticals <i>Parsippany, NJ</i>	hypogonadism	Phase III (973) 898-1042
testosterone transdermal	VIVUS <i>Mountain View, CA</i>	low sexual desire in women	Phase II (650) 934-5200
testosterone undecanoate	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	hypogonadism	Phase II (888) 842-2937
transdermal testosterone gel	BioSante Pharmaceuticals <i>Lincolnshire, IL</i>	female sexual dysfunction, hypogonadism	Phase III (847) 478-0500
udenafil	Dong-A PharmTech <i>Seoul, South Korea</i>	erectile dysfunction	Phase II
<b>Vitaros®</b> alprostadil topical	NexMed <i>East Windsor, NJ</i>	erectile dysfunction	application submitted (609) 371-8123
VML-670	Eli Lilly <i>Indianapolis, IN</i>	female sexual dysfunction, male sexual dysfunction	Phase II (800) 545-5979
<b>Zoraxel™</b>	Rexahn Pharmaceuticals <i>Rockville, MD</i>	erectile dysfunction	Phase II (240) 268-5300

## SKIN CONDITIONS

Product Name	Sponsor	Indication	Development Status
ABT-874	Abbott Laboratories <i>Abbott Park, IL</i>	plaque psoriasis (see also gastrointestinal)	Phase III (847) 937-6100
AGN-194310	Allergan <i>Irvine, CA</i>	psoriasis	Phase III (800) 433-8871
AN-0128	Anacor Pharmaceuticals <i>Palo Alto, CA</i>	psoriasis	Phase I/II (650) 543-7500
AN-2728	Anacor Pharmaceuticals <i>Palo Alto, CA</i>	psoriasis	Phase II (650) 543-7500
anti-interferon-gammaoly polyclonal antibody	Advanced Biotherapy <i>Chicago, IL</i>	psoriasis	in clinical trials (312) 427-1912
apremilast	Celgene <i>Summit, NJ</i>	psoriasis, psoriatic arthritis	Phase II (908) 673-9000

## SKIN CONDITIONS

Product Name	Sponsor	Indication	Development Status
BCX-4208	BioCryst Pharmaceuticals <i>Birmingham, AL</i> Roche <i>Nutley, NJ</i>	plaque psoriasis	Phase II (205) 444-4600 (973) 235-5000
becocalcidiol	Galderma Laboratories <i>Fort Worth, TX</i>	psoriasis	Phase II (817) 961-5000
BIO-236	Enhance Biotech <i>New York, NY</i>	skin aging	Phase I (212) 897-6849
CH-1504	Chelsea Therapeutics <i>Charlotte, NC</i>	psoriasis (see also rheumatoid arthritis)	Phase I (704) 341-1516
CP-690550	Pfizer <i>New York, NY</i>	plaque psoriasis (see also gastrointestinal, rheumatoid arthritis)	Phase II (860) 732-5156
CRx-191	CombinatoRx <i>Cambridge, MA</i>	psoriasis	Phase II (617) 301-7000
CRx-197	CombinatoRx <i>Cambridge, MA</i>	plaque psoriasis	Phase II (617) 301-7000
doramapimod (BIRB796)	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	psoriasis (see also gastrointestinal, rheumatoid arthritis)	Phase II/III (203) 798-0000
E6201	Eisai Medical Research <i>Ridgefield Park, NJ</i>	psoriasis	Phase II (888) 422-4743
golimumab	Centocor <i>Horsham, PA</i> Medarex <i>Princeton, MA</i>	psoriatic arthritis (see also gastrointestinal, rheumatoid arthritis)	application submitted (610) 651-6000
GPX-150	Gem Pharmaceuticals <i>Birmingham, AL</i>	psoriasis	Phase I/II (205) 982-0320
INCB-18424	Incyte <i>Wilmington, DE</i>	psoriasis (see also rheumatoid arthritis)	Phase II (302) 498-6700
lestaurtinib	Cephalon <i>Frazer, PA</i>	plaque psoriasis	Phase II (610) 344-0200
<b>Levulan</b> <sup>®</sup> aminolevulinic acid	DUSA <i>Wilmington, MA</i>	psoriasis	in clinical trials (978) 657-7500
LIF-313	Enhance Lifesciences <i>New York, NY</i>	psoriasis	Phase I (212) 561-1716
MEDI-545	Medarex <i>Princeton, NJ</i> MedImmune <i>Gaithersburg, MD</i>	psoriasis	Phase I (609) 430-2880 (301) 398-0000
MM-093	Merrimack Pharmaceuticals <i>Cambridge, MA</i>	psoriasis (see also rheumatoid arthritis)	Phase II (617) 441-1000
MV9411	Miravant Medical Technologies <i>Santa Barbara, CA</i>	psoriasis	Phase II (888) 768-5501

## SKIN CONDITIONS

Product Name	Sponsor	Indication	Development Status
otelixizumab	Tolerx Cambridge, MA	psoriasis (see also diabetes)	Phase I completed (617) 354-8100
paclitaxel	Angiotech Pharmaceuticals Vancouver, BC	psoriasis (see also lung, rheumatoid arthritis)	Phase II (604) 221-7676
PH-10	Provectus Pharmaceuticals Knoxville, TN	psoriasis	Phase II (866) 594-5999
R348	Rigel Pharmaceuticals South San Francisco, CA	psoriasis (see also rheumatoid arthritis)	Phase I (650) 624-1100
RWJ-445380	Johnson & Johnson Pharmaceutical Research & Development Raritan, NJ	plaque psoriasis (see also rheumatoid arthritis)	Phase II (800) 817-5286
sirolimus	Wyeth Pharmaceuticals Collegeville, PA	psoriasis	Phase I (800) 934-5556
stem cell protectant	ProCertus BioPharm Madison, WI	dermatitis (prevention)	Phase I (608) 277-7950
SUN-13834	Asubio Pharmaceuticals Rochelle Park, NJ	atopic dermatitis	Phase II (201) 368-5020
teriparatide topical	Manhattan Pharmaceuticals New York, NY	psoriasis	Phase II (212) 582-3950
tisocalcitate	Bayer HealthCare Pharmaceuticals Wayne, NJ	psoriasis	Phase II (888) 842-2937
ustekinumab	Centocor Horsham, PA Medarex Princeton, NJ	plaque psoriasis (see also gastrointestinal)	application submitted (610) 651-6000
		psoriatic arthritis	Phase II (610) 651-6000
VTP-201227	Vitae Pharmaceuticals Fort Washington, PA	psoriasis	Phase II (215) 461-2000
VX-765	Vertex Pharmaceuticals Cambridge, MA	psoriasis	Phase II (617) 444-6777

## SLEEP DISORDERS

Product Name	Sponsor	Indication	Development Status
649868 (hypocretin receptor antagonist)	GlaxoSmithKline Rsch. Triangle Park, NC	sleep disorders	Phase II (888) 825-5249
almorexant	Actelion Pharmaceuticals US South San Francisco, CA GlaxoSmithKline Rsch. Triangle Park, NC	insomnia in elderly	Phase II (650) 624-6900 (888) 825-5249

## SLEEP DISORDERS

Product Name	Sponsor	Indication	Development Status
APD-125	Arena Pharmaceuticals <i>San Diego, CA</i>	insomnia	Phase II (858) 452-7200
aplindore	Neurogen <i>Branford, CT</i>	restless legs syndrome (see also Parkinson's)	Phase II (203) 488-8201
AZ-007 (zaleplon inhalation)	Alexza Pharmaceuticals <i>Mountain View, CA</i>	insomnia	Phase I (650) 944-7000
CX717	Cortex Pharmaceuticals <i>Irvine, CA</i>	sleep disorders (see also Alzheimer's)	Phase II (949) 727-3157
eplivanserin (5-HT <sub>2A</sub> antagonist)	sanofi-aventis <i>Bridgewater, NJ</i>	insomnia	Phase III (800) 633-1610
esmirtazapine	Schering-Plough <i>Kenilworth, NJ</i>	insomnia	Phase III (908) 298-5000
EVT-201	Evotec <i>North Potomac, MD</i>	insomnia in elderly	Phase II completed (240) 683-1199
<b>Gabitril</b> <sup>®</sup> tiagabine	Cephalon <i>Frazer, PA</i>	insomnia (see also pain)	Phase II (610) 344-0200
indiplon (controlled-release)	Neurocrine Biosciences <i>San Diego, CA</i>	insomnia	application submitted (858) 658-7600
indiplon (immediate release)	Neurocrine Biosciences <i>San Diego, CA</i>	insomnia	application submitted (858) 617-7600
<b>Intermezzo</b> <sup>™</sup> zolpidem (sublingual)	Transcept Pharmaceuticals <i>Pt. Richmond, CA</i>	insomnia	application submitted (510) 215-3500
<b>Invega</b> <sup>™</sup> paliperidone	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	insomnia	Phase II (800) 817-5286
ITI-007	Intra-Cellular Therapies <i>New York, NY</i>	insomnia	Phase II (212) 923-3344
		----- sleep disorders	Phase I (212) 923-3344
LY-156735	Tikvah Therapeutics <i>Atlanta, GA</i>	sleep disorders	Phase II (404) 920-3180
LY-2422347 (pruvanserin)	Eli Lilly <i>Indianapolis, IN</i>	insomnia	Phase II (800) 545-5979
LY-2624803	Eli Lilly <i>Indianapolis, IN</i>	insomnia	Phase II (800) 545-5979
<b>Lyrica</b> <sup>®</sup> pregabalin	Pfizer <i>New York, NY</i>	restless legs syndrome (see also pain)	Phase II (860) 732-5156
melatonin (controlled-release) <b>(Orphan Drug)</b>	Neurim Pharmaceuticals <i>Tel-Aviv, Israel</i>	sleep disorders	Phase III www.neurim.com
MK-0454	Merck <i>Whitehouse Station, NJ</i>	insomnia	Phase I (800) 672-6372

## SLEEP DISORDERS

Product Name	Sponsor	Indication	Development Status
MK-8998	Merck <i>Whitehouse Station, NJ</i>	insomnia	Phase I (800) 672-6372
NBI-75043	Neurocrine Biosciences <i>San Diego, CA</i>	insomnia	Phase I (858) 617-7600
<b>Neupro</b> <sup>®</sup> rotigotine transdermal	Schwarz Pharma <i>Mequon, WI</i>	restless legs syndrome (see also Parkinson's)	application submitted (800) 558-5114
PD-200390	Pfizer <i>New York, NY</i>	insomnia	Phase II (860) 732-5156
pimavanserin (ACP-103)	ACADIA Pharmaceuticals <i>San Diego, CA</i>	insomnia	Phase II (858) 558-2871
<b>ReQuip</b> <sup>®</sup> XR ropinirole extended-release	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	restless legs syndrome	application submitted (888) 825-5249
ropinirole transdermal gel	Antares Pharma <i>Ewing, NJ</i> Jazz Pharmaceuticals <i>Palo Alto, CA</i>	restless legs syndrome	Phase I (609) 359-3020 (650) 496-3777
rotigotine intransal	Schwarz Pharma <i>Mequon, WI</i>	restless legs syndrome	Phase II (800) 558-5114
<b>Rozerem</b> <sup>™</sup> ramelteon	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	circadian rhythm sleep disorders	Phase II (224) 554-6500
safinamide	EMD Serono <i>Rockland, MA</i>	restless legs syndrome (see also Alzheimer's, Parkinson's)	Phase II (800) 283-8088
<b>Silenor</b> <sup>™</sup> doxepin low dose	Somaxon Pharmaceuticals <i>San Diego, CA</i>	insomnia	application submitted (858) 509-3670
<b>Solzira</b> <sup>™</sup> gabapentin enacarbil	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> XenoPort <i>Santa Clara, CA</i>	restless legs syndrome (see also pain)	application submitted (888) 825-5249
<b>Sublinox</b> <sup>™</sup> zolpidem sublingual	Meda Pharmaceuticals <i>Somerset, NJ</i> Orexo <i>Uppsala, Sweden</i>	insomnia	application submitted (732) 564-2200
VEC-162 (tasimelteon)	Vanda Pharmaceuticals <i>Rockville, MD</i>	insomnia	Phase III (240) 599-4500
volinanserin (5-HT <sub>2A</sub> antagonist)	sanofi-aventis <i>Bridgewater, NJ</i>	insomnia	Phase III (800) 633-1610
VSF-173	Vanda Pharmaceuticals <i>Rockville, MD</i>	induced excessive sleepiness	Phase II (240) 599-4500
zaleplon controlled-release	King Pharmaceuticals <i>Bristol, TN</i>	insomnia	Phase II (800) 776-3637
<b>ZolpiMist</b> <sup>™</sup> zolpidem oral spray	NovaDel Pharma <i>Flemington, NJ</i>	insomnia	application submitted (908) 782-3431

## OTHER

Product Name	Sponsor	Indication	Development Status
ANGX-1039	Angiogenix <i>Burlingame, CA</i>	intermittent claudication	Phase I (650) 552-0072
ASP-2151	Astellas Pharma US <i>Deerfield, IL</i>	herpes zoster (shingles)	Phase II (800) 727-7003
carisbamate	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	essential tremor (see also epilepsy, pain)	Phase II (800) 817-5286
FV-100	Inhibitex <i>Alpharetta, GA</i>	herpes zoster (shingles)	Phase I (678) 746-1100
histamine dihydrochloride topical	EpiCept <i>Tarrytown, NY</i>	herpes zoster (shingles)	Phase II (914) 606-3500
INDI-702	Indigo Pharmaceuticals <i>New York, NY</i>	intermittent claudication	Phase II (212) 554-4283
pneumococcal vaccine conjugate 13-valent	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	pneumococcal infections in high-risk populations	Phase III (800) 934-5556
<b>Prevnar® Adult</b> pneumococcal vaccine conjugate 7-valent	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	pneumococcal infections in elderly patients	Phase III (800) 934-5556
satavaptan (V2 antagonist)	sanofi-aventis <i>Bridgewater, NJ</i>	cirrhosis	Phase III (800) 633-1610
sorivudine topical	aRigen Pharmaceuticals <i>Tokyo, Japan</i> Janus Pharmaceuticals <i>Pasadena, CA</i>	herpes zoster (shingles)	Phase II (626) 568-0762
tacrolimus	Astellas Pharma US <i>Deerfield, IL</i>	primary billiary cirrhosis (see also lung)	Phase II (800) 727-7003
V212	Merck <i>Whitehouse Station, NJ</i>	herpes zoster (shingles) (prevention)	Phase I (800) 672-6372
<b>ZFP-Therapeutics™</b> EWA 401	Sangamo BioScience <i>Richmond, CA</i>	intermittent claudication	Phase I (510) 970-6000

The content of this report has been obtained through industry sources and the Adis “R&D Insight” database based on the latest information. **Report current as of November 10, 2008.** The information may not be comprehensive. For more specific information about a particular product, contact the individual company directly or go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov). The entire series of *Medicines in Development* is available on PhRMA’s web site.

A publication of PhRMA’s Communications & Public Affairs Department. (202) 835-3460

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**application submitted**—An application for marketing has been submitted by the company to the Food and Drug Administration (FDA).

**benign prostatic hyperplasia (BPH)**—The noncancerous enlargement of the prostate gland that occurs in almost all men as they age. Enlargement eventually can obstruct the bladder, causing urination difficulties. BPH can lead ultimately to severe infection of the urinary tract and kidney failure.

**bronchitis**—Inflammation of the airways (bronchi) that connect the windpipe (trachea) to the lungs. Acute bronchitis comes on suddenly and usually clears up in a few days. The chronic form persists over a long period and may recur over several years.

**chronic obstructive pulmonary disease (COPD)**—The combination of chronic bronchitis and emphysema, in which there is a persistent disruption of airflow out of the lungs and eventual hypoxemia (low level of oxygen in the blood).

**colitis**—Inflammation of the colon (large intestine) causing diarrhea, usually with blood and mucus, and sometimes with abdominal pain and fever. Colitis may be due to a variety of causes, including infection by a virus, amoeba, or a bacterium that produces toxins that irritate the intestinal lining. Antibiotic therapy for more than two weeks may result in a form of colitis caused by the bacterium *Clostridium difficile*, which produces an irritating toxin. **Ulcerative colitis** is a chronic inflammation and ulceration of the lining of the colon and rectum. It causes bloody diarrhea and mainly involves the left colon.

**Crohn's disease**—A subacute chronic gastrointestinal disorder, involving the small intestine, characterized by patchy deep ulcers that may cause fistulas and a narrowing and thickening of the bowel.

**dementia**—A general mental deterioration due to organic or psychological factors.

**depression**—Present in all age groups, in seniors it may result from a number of biologic, sociologic and psychologic factors associated with aging: decreasing mental and physical abilities, multiple medical problems, chronic pain, loss of independence and change in lifestyle. Early dementia and depression may be confused with one another. It is characterized by: loss of interest or pleasure in usual activities, sadness, feelings of hopelessness, irritability, poor appetite, insomnia, loss of energy and lack of concentration. Suicidal thoughts may occur.

**diabetes**—A chronic disease characterized by abnormal insulin secretion from the pancreas, thereby causing problems in metabolizing sugar. Symptoms may include: excessive thirst, hunger, urination and weight loss. Diet, exercise and weight loss are often sufficient to control this disease. Insulin treatment is needed for only a minority of elderly diabetics. Oral drugs are useful in some patients.

**dry eyes**—Dry eyes occur when the tear glands produce fewer tears. Symptoms range from mild irritation and a sensation of something in the eye to severe discomfort and sensitivity to light. It is more common with older age.

**dyskinesia**—Difficulty or distortion in performing voluntary movements, such as a tic, chorea, or spasm. The term may be used in relation to Parkinson's disease and other disorders. Dyskinesia also can occur as a side effect of certain medications, such as L-dopa and antipsychotics.

**emphysema**—An enlargement of the tiny air sacs of the lungs (alveoli) and the destruction of their walls, which causes structural and permanent narrowing of airflow.

**female sexual arousal disorder**—Female sexual arousal disorder (FSAD) occurs when a woman is continually unable to attain or maintain arousal and lubrication during intercourse, is unable to reach orgasm, or has no desire for sexual intercourse.

**gastroparesis**—"Stomach paralysis" is a disorder in which the stomach takes too long to empty its contents. It is an abnormal function of the stomach without any physical evidence of obstruction. The most common symptoms are nausea and vomiting especially after eating.

**glaucoma**—An eye disease associated with increased pressure within the eyeball. If untreated, it may lead to permanent and complete blindness.

**herpes zoster**—Also called "shingles," an outbreak of rash or blisters on the skin that is caused by the same virus that causes chicken pox — the varicella-zoster virus. The first sign of shingles is often burning or tingling pain, or sometimes numbness, in or under the skin. After several days, a rash of small fluid-filled blisters, reminiscent of chickenpox, appears on reddened skin. The pain associated with shingles can be intense and is often described as "unrelenting." Anyone who has had chickenpox is at risk for shingles.

**hyperparathyroidism**—Occurs when one or more of the parathyroid glands becomes enlarged and overactive, producing too much parathyroid hormone (PTH). When this happens, the excess parathyroid hormone causes a high level of calcium to be released in the blood. Since the bones are the primary source of this calcium, hyperparathyroidism can result in excess bone loss or osteoporosis. If the condition is successfully treated, the bone loss can usually be reversed and bone density can be restored. Most cases (85%) of hyperparathyroidism are the result of a single parathyroid gland malfunctioning and developing into a benign tumor, known as an adenoma. In nearly all other cases (15%), two or more glands enlarge, again in a benign fashion, a condition called hyperplasia.

**hypogonadism**—Underactivity of the gonads (ovaries and testes), which may be caused by disorders of these sex glands or by a pituitary gland disorder.

**ileus**—Partial or complete non-mechanical blockage of the small and/or large intestine.

**influenza**—A viral infection of the respiratory tract that causes fever, headache, muscle ache and weakness. There are three main types of **influenza virus**—A, B and C. A person who has had an attack with the type C virus acquires antibodies that provide immunity against that type for life. Anyone who has been infected with a certain strain of the type A or B viruses acquires immunity to that strain. Both the A- and B-type viruses occasionally alter to produce new strains that may be able to overcome immunity. Type B is fairly stable, but type A is highly unstable, and new strains of it arise constantly throughout the world.

**intermittent claudication**—Cramp-like pain in one or both legs which develops on walking and may eventually cause a limp. The usual cause is blockage or narrowing of arteries in the legs due to atherosclerosis.

**irritable bowel syndrome**—A disorder of motility (movement) of the entire gastrointestinal tract that produces abdominal pain, constipation or diarrhea.

**macular degeneration**—Degeneration of the macula, the central portion of the retina that allows for fine visual detail. Risk factors for **age-related macular degeneration** (AMD) include genetics, smoking, diet, light-colored eyes, and age (55 and older). There are two stages of AMD: dry and wet. Dry AMD accounts for approximately 90 percent of all cases and is characterized by an accumulation of fatty deposits (drusen) beneath the macula. Initially, patients with dry AMD notice that straight lines appear wavy or that letters become distorted. As the deposits accumulate, central vision becomes more impaired, making it difficult to read or perform tasks requiring hand-eye coordination. Wet AMD accounts for about 10 percent of all AMD cases and is caused by abnormal blood vessel growth beneath the

macula. These blood vessels leak fluid and blood into the retina, causing severe, rapid loss of central vision. Dry AMD may precede the development of wet AMD. Although dry AMD is currently untreatable, wet AMD is treatable with recently approved photodynamic therapy. Early detection is critical to prevent catastrophic vision loss.

**neuropathic pain**—Caused by disease, inflammation, or damage to the peripheral nerves, which connect the central nervous system (brain and spinal cord) to the sense organs, muscles, glands and internal organs.

**osteoarthritis**—A degenerative joint disease of unknown cause. It is characterized by degeneration of the cartilage that lines joints and by the formation of reactive bony outgrowths at the boundary of a joint. This leads to pain and loss of joint function. It is the most common form of joint disease.

**osteoporosis**—The most common metabolic bone disease in older people. It may be associated with other diseases such as rheumatoid arthritis or with the use of medication such as corticosteroids. A reduction in bone mass leads to fractures, especially of the vertebrae, hips and wrists.

**Parkinson's disease**—Chronic neurologic disease of unknown cause, characterized by tremors, rigidity and an abnormal gait. There is an imbalance in the body of dopamine and acetylcholine neurotransmitters normally present in the brain. Some patients with advanced disease develop dementia. It is one of the most common chronic diseases of later life.

**Phase I**—Safety testing and pharmacological profiling in humans.

**Phase II**—Effectiveness and safety testing in humans.

**Phase III**—Extensive clinical trials to demonstrate safety and efficacy in humans.

**pneumonia**—Inflammation of the lungs due to infection, usually by viruses or bacteria. It is the sixth

most common cause of death in the United States, primarily because it is a common complication of any serious illness.

**psoriasis**—A common skin disease characterized by thickened patches of inflamed, red skin often covered by silvery scales.

**restless legs syndrome**—Restless legs syndrome is an overwhelming urge to move the legs usually caused by uncomfortable or unpleasant sensations in the legs. The sensations have the following features: occur during periods of inactivity; become more sensitive in the evening and at night; are relieved by movement of the limb; often cause difficulty staying or falling asleep, which leads to feelings of daytime tiredness or fatigue; and may cause involuntary jerking of the limbs during sleep and sometimes during wakefulness.

**retinitis pigmentosa**—A progressive degeneration of the retina (part of the eye) which affects night vision and peripheral vision.

**rheumatoid arthritis**—A type of arthritis that particularly attacks the small joints of the hands, wrists and feet. With this autoimmune disorder, the joints become painful, swollen, stiff and, in severe cases, deformed.

**sepsis**—A severe bacterial infection involving the bloodstream. Sepsis has a high mortality rate unless promptly treated with intravenous antibiotics.

**short bowel syndrome**—The mal-absorptive condition that arises after significant segments of the small intestine are removed. Some of the most common causes in adults are Crohn's disease, radiation enteritis and trauma.

**urinary incontinence**—Uncontrollable, involuntary urination, often due to neurologic disease (such as Alzheimer's), an enlarged prostate, weak pelvic muscles or improper use of medication.

# MORE THAN 2,000 MEDICINES IN DEVELOPMENT FOR OLDER AMERICANS

A series of surveys by the Pharmaceutical Research and Manufacturers of America (PhRMA) has found that researchers are currently working on more than 2,000 new medicines to tackle the three leading causes of death among seniors—heart disease, cancer, and stroke—and major causes of disability among seniors, including diabetes, Alzheimer’s disease, arthritis, Parkinson’s disease and others.

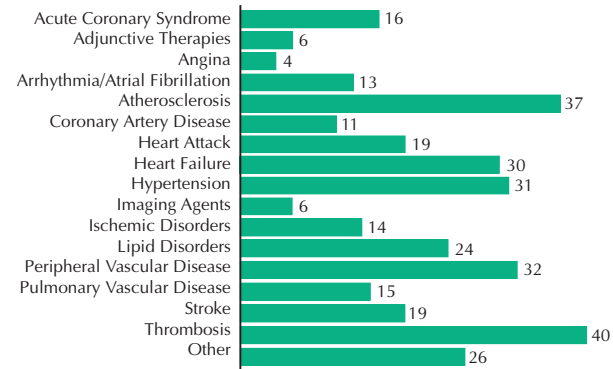
The latest Medicines in Development surveys for Cancer, Heart Disease/Stroke and Older Americans show:

- 277 medicines in development to treat or prevent heart disease and stroke
- 750 medicines in development to fight cancer
- 1,026 new medicines in development that target such debilitating diseases of aging as respiratory and lung disorders (166 medicines), Alzheimer’s disease/dementias (91 medicines), diabetes (150 medicines), arthritis (82 medicines), and osteoporosis (30 medicines).

All of the medicines included in the surveys are either in clinical trials or awaiting approval by the Food and Drug Administration.

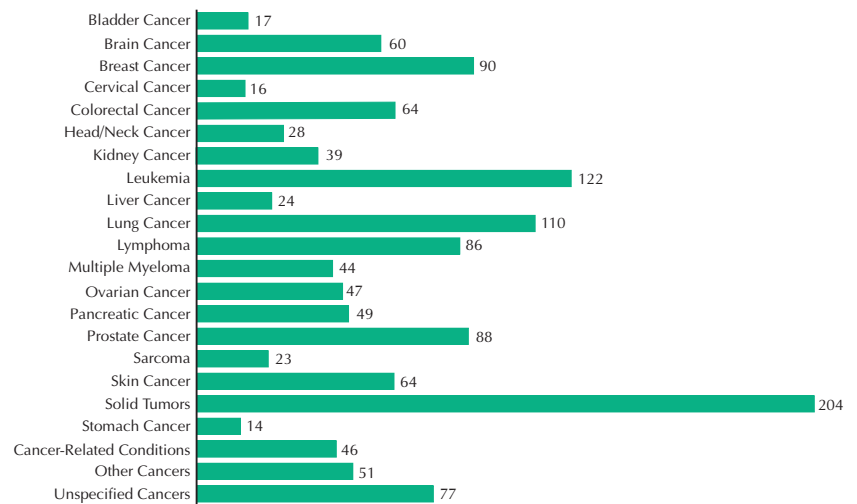
The PhRMA surveys are all available on the website at [www.phrma.org](http://www.phrma.org). Click on “New Medicines.”

## MEDICINES IN DEVELOPMENT FOR HEART DISEASE AND STROKE\*



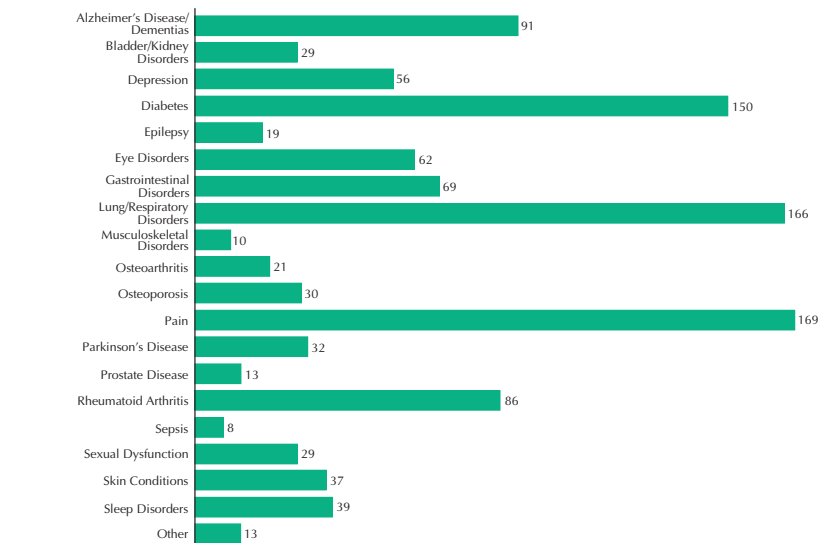
\*Some medicines are listed in more than one category.

## MEDICINES IN DEVELOPMENT FOR CANCER\*



\*Some medicines are listed in more than one category.

## MEDICINES IN DEVELOPMENT FOR OLDER AMERICANS\*



\*Some medicines are listed in more than one category.

# 10 LEADING CAUSES OF DEATH IN AMERICANS AGE 65 AND OLDER, 2004

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1. Heart Disease (533,302)
2. Cancer (385,847)
3. Cerebrovascular Disease (130,538)
4. Chronic Lower Respiratory Diseases (105,197)
5. Alzheimer's Disease (65,313)
6. Diabetes Mellitus (53,956)
7. Influenza and Pneumonia (52,760)
8. Nephritis (35,105)
9. Accidents (unintentional injuries) (35,020)
10. Septicemia (25,644)

Source: *Deaths: Final Data for 2004*, National Vital Statistics Reports, Vol. 56, No. 5, November 20, 2007, National Center for Health Statistics, Centers for Disease Control.

## SELECTED FACTS ABOUT DISEASES AFFECTING AMERICANS AGE 65 AND OLDER

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### Statistical Profile of Older Americans<sup>1</sup>

- The older population (65 and older) numbered 37.3 million in 2006, an increase of 3.4 million, or 10 percent, since 1996. About 1 in 8, or 12.4 percent, of the population is an older American.
- Older women outnumber older men, 21.6 million to 15.7, respectively.
- The 85 and older population numbered 5.3 million in 2006 and is projected to increase to 8.9 million in 2030.
- In 2006, 39 percent of non-institutionalized older people assessed their health as excellent or very good (compared with 65.1 percent for people ages 18-64).
- Most older people have at least one chronic condition and many have multiple conditions. Among the most frequently occurring conditions of the elderly from 2004-2005 were: **high blood pressure** (48 percent), **arthritis** (47 percent), **heart disease** (29 percent), **cancer** (20 percent), **diabetes** (16 percent), and **sinusitis** (14 percent).

### Acute Myocardial Infarction (Heart Attack)<sup>2</sup>

- **Coronary heart disease (CHD-heart attack**, angina pectoris or both) caused one of every five deaths in 2004. The average age of a person having a first heart attack is 64.5 for men and 70.4 for women. About 82 percent of people who die of CHD are age 65 or older.
- In 2008, the estimated direct and indirect costs of **CHD** are \$156.4 billion.

### Age-Related Macular Degeneration (AMD)<sup>3</sup>

- The leading cause of blindness among white Americans is **AMD**, accounting for 54 percent of all blindness. AMD is strongly associated with increasing age, particularly after age 60. AMD rises dramatically in whites over age 80—more than 1 in 10 white Americans in that age group has vision loss from AMD.
- **AMD** currently affects 1.8 million people in this country. Due to the rapidly aging U.S. population, that number will increase to almost 3 million by 2020.

### Alzheimer's Disease (AD)<sup>4</sup>

- Today, more than 5 million people are living with **Alzheimer's**—every 72 seconds, someone develops the disease. Some 4.9 million people with Alzheimer's are age 65 and older, but at least 500,000 people younger than age 65 either have early-onset Alzheimer's or another **dementia**.

# SELECTED FACTS ABOUT DISEASES AFFECTING AMERICANS AGE 65 AND OLDER

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## Alzheimer's Disease (AD)<sup>4</sup> (continued)

- **Alzheimer's disease** is the most common **dementia**, accounting for 50 percent to 70 percent of cases. **Vascular dementia** (also called multi-infarct dementia, post-stroke dementia, or vascular cognitive impairment) is widely considered the second most common type after Alzheimer's.
  - In 2000, an estimated 411,000 new cases of **Alzheimer's** were diagnosed. That number is expected to increase to 454,000 new cases a year by 2010; 615,000 annually by 2030; and 959,000 new cases a year by 2050. By that year, the number of people age 65 and older with Alzheimer's could be as high as 16 million unless researchers find a way to prevent or treat the disease.
  - In 2004, **Alzheimer's** was listed as the "underlying cause of death" for 65,829 Americans. From 2000-2004, deaths from Alzheimer's increased by 32.8 percent, while the number one cause of death, heart disease, decreased by 8 percent.
  - The direct and indirect costs of **Alzheimer's** and other **dementias** amount to more than \$148 billion annually. Costs to businesses for employees who are caregivers for people with **Alzheimer's** and other **dementias** amount to \$36.5 billion due to lost productivity, missed work, and costs to replace workers who leave their jobs to meet the demands of caregiving.
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## Asthma<sup>5</sup>

- Approximately 22.9 million Americans had **asthma** in 2006, including almost 2.5 million people over the age of 65. That year, more than 1 million people over the age of 65 had an asthma attack or episode.
  - The annual direct health care cost of **asthma** is approximately \$14.7 billion; indirect costs (e.g., lost productivity) add another \$5 billion, for a total of \$19.7 billion dollars. Prescription drugs represented the largest single direct cost, at \$6.2 billion.
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## Cancer<sup>6</sup>

- The risk of **cancer** increases with age—about 77 percent of all cancers are diagnosed at age 55 and older.
  - The primary risk factor for **colorectal cancer** is age, with more than 90 percent of cases diagnosed in individuals over age 50.
  - The risk for **ovarian cancer** increases with age and peaks in the late 70s. Women younger than age 65 are about twice as likely to survive five years following diagnosis than women 65 and older, 56 percent and 29 percent, respectively.
  - About 64 percent of all **prostate cancer** cases are diagnosed in men over age 65. African-American men and Jamaican men of African descent have the highest prostate cancer incidence rates in the world.
  - In 2007, the estimated overall costs for **cancer** were \$219.2 billion.
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## Cardiovascular Diseases (CVD)<sup>2</sup>

- Since 1900, **CVD** has been the number one killer in this country every year but 1918. Nearly 2,400 Americans die of CVD each day, an average of one death every 37 seconds. CVD claims about as many lives each year as the next five leading causes of death combined (**cancer, chronic lower respiratory diseases, accidents, and diabetes**).
- Of the 80.7 million American adults who have one or more types of **CVD**, 38.2 million are estimated to be age 60 or older. In 1999, 23 percent of nursing home residents in that age group had a primary diagnosis of CVD at admission.
- In 2008, the estimated direct and indirect costs of **CVD** are \$448.5 billion.

# SELECTED FACTS ABOUT DISEASES AFFECTING AMERICANS AGE 65 AND OLDER

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## Chronic Obstructive Pulmonary Disease (COPD)<sup>5</sup>

- In 2006, an estimated 12.1 million adults age 18 and older had **COPD** (an umbrella term for a large group of lung diseases, chiefly **chronic bronchitis** and **emphysema**).
  - In 2006, an estimated 9.5 million Americans reported a physician diagnosis of **chronic bronchitis**. The highest prevalence rate was in the over 65 population (60.9 per 1,000 people).
  - The **emphysema** prevalence rate is very low in those under age 45. Of the estimated 4.1 million Americans ever diagnosed with emphysema, 93 percent were 45 or older. In 2006, the emphysema rate in whites over age 65 (60.1 per 1,000 people) was more than 2.3 times greater than that in the population between 45 and 64 (26.3 per 1,000).
  - **COPD** is an important cause of hospitalization in the older U.S. population. Some 65 percent of hospital discharges were in the 65 and older population in 2005. The discharge rate for the population over age 65 (126.9 per 10,000 people) was significantly different than the rate for any other group. For example, the rate in the over age 65 group was four times higher than that in the 45-64 age group (31.4 per 10,000).
  - **Chronic bronchitis** and **emphysema** take a heavy toll on the U.S. economy—\$42.6 billion in 2007.
- 

## Congestive Heart Failure (CHF)<sup>2</sup>

- **Congestive heart failure (CHF)** incidence approaches 10 per 1,000 population after age 65. In 2004, CHF total mention mortality was 284,365. CHF was listed as the underlying cause in 57,120 of those deaths.
  - In 2003, the estimated direct and indirect costs for **CHF** are \$34.8 billion.
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## Crohn's Disease<sup>7</sup>

- While **Crohn's disease** is often thought of as a disease of the young, about 25 percent of new cases are diagnosed in individuals over age 60.
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## Depression

- Depression in its many forms affects more than 6.5 million of the 35 million Americans who are age 65 or older. Depression in older people is closely associated with dependency and disability.<sup>8</sup>
  - Symptoms of clinical depression can be triggered by other chronic illnesses common in later life, such as **Alzheimer's disease, Parkinson's disease, heart disease, cancer, and arthritis**. For example, nearly one-fourth of the 600,000 people who experience a **stroke** in a given year will experience clinical depression.<sup>9</sup>
  - **Depression** is one of the conditions most commonly associated with suicide in older adults. Although they comprise only 12 percent of the U.S. population, people age 65 and older accounted for 16 percent of suicide deaths in 2004. That year, non-Hispanic white men age 85 and older were most likely to die by suicide, with a rate of 49.8 suicide deaths per 100,000 people in that age group.<sup>10</sup>
  - Older patients with symptoms of **depression** have roughly 50 percent higher health-care costs than non-depressed seniors.<sup>9</sup>
- 

## Diabetes

- Among people age 60 and older, 12.2 million, or 23.1%, have **diabetes**.<sup>11</sup>
  - The total annual economic cost of **diabetes** in 2007 was estimated to be \$174 billion.<sup>12</sup>
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## Dry Eyes<sup>3</sup>

- Nearly 5 million Americans 50 years of age and older are estimated to have **dry eye syndrome**. Of these, more than 3 million are women and more than 1.5 million are men.

# SELECTED FACTS ABOUT DISEASES AFFECTING AMERICANS AGE 65 AND OLDER

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## Epilepsy<sup>13</sup>

- **Epilepsy** and seizures affect more than 3 million Americans of all ages. Incidence is highest under the age of 2 and over age 65. Some 570,000 people over the age of 65 have epilepsy.
  - **Epilepsy's** estimated annual direct and indirect costs are \$12.5 billion.
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## Glaucoma

- Open-angle **glaucoma**, the most common form of the disease, affects more than 2.2 million Americans age 40 and older.<sup>14</sup>
  - Those at highest risk for **glaucoma** are African Americans over age 40 and everyone over age 60, especially Mexican Americans. The prevalence of glaucoma rises rapidly in Hispanics over age 65.<sup>3</sup>
  - When comparing African Americans with Caucasians, studies show that glaucoma is five times more likely to occur in blacks than in whites and about four times more likely to cause blindness in blacks.<sup>3</sup>
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## High Blood Pressure (HBP)<sup>2</sup>

- The estimated 2005 prevalence for **high blood pressure (HBP)** was 73 million people (about 34 million males and 39 million females). Nearly one in three U.S. adults has HBP. A higher percentage of men than women have HBP until age 45. From ages 45-54, the percentage of men and women is similar. After that, a much higher percentage of women have HBP than men do.
  - In 2004, **HBP** mortality was 54,707 (23,099 males, 31,608 females). HBP total mention mortality was about 300,000.
  - In 2008, the estimated direct and indirect costs of **HBP** are \$69.4 billion.
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## Incontinence

- **Urinary incontinence** affects an estimated 38 percent of women and 17 percent of men ages 60 or older.<sup>15</sup>
  - Of the elderly people living at home or in long-term care facilities, 50 percent or more are **incontinent**.<sup>16</sup>
  - The medical and work-related costs of **urinary incontinence** are estimated to be \$26 billion per year.<sup>15</sup>
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## Influenza and Pneumonia<sup>5</sup>

- **Influenza and pneumonia** are most likely to require hospitalization in those over age 65. Data from 2005 show that people ages 65 and older accounted for 60 percent of the total number of pneumonia hospital discharges (the diagnosis made upon leaving a hospital stay). The number (36,000) and rate (9.8 per 10,000 people) of influenza discharges were both highest in those ages 65 and older.
  - For the 65 and older population, **pneumonia and influenza** were the sixth leading cause of death in 2005. Nearly 90 percent of deaths due to these diseases occur in that age group.
  - Together, **pneumonia and influenza** cost the economy \$40.2 billion in 2007.
- 

## Leukemia<sup>6</sup>

- Although often thought of as primarily a childhood disease, leukemia is diagnosed 10 times more often in adults than in children. In adults, the most common types are **acute myeloid leukemia** (approximately 13,290 cases in 2008) and **chronic lymphocytic leukemia** (approximately 15,110 cases).
- 

## Osteoarthritis (OA)

- **Osteoarthritis**, the most common chronic condition of the joints, affects approximately 33 million Americans. Although it occurs in people of all ages, it is most common in people older than age 65, affecting up to 80 percent of the elderly population.<sup>17</sup> It is the leading cause of disability in that age group.<sup>16</sup>

# SELECTED FACTS ABOUT DISEASES AFFECTING AMERICANS AGE 65 AND OLDER

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## Osteoporosis

- **Osteoporosis** and low bone mass are a major public health threat for an estimated 44 million Americans, or 55 percent of people age 50 and older. An estimated 10 million people have osteoporosis today, 80 percent of whom are women, and 34 million more people are estimated to have low bone mass, placing them at increased risk for osteoporosis.<sup>18</sup>
  - In 2005, **osteoporosis**-related fractures were responsible for an estimated \$19 billion in costs. By 2025, experts predict that these costs will rise to approximately \$25.3 billion.<sup>19</sup>
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## Pain<sup>20</sup>

- **Pain** is the number one complaint of older Americans. One in five older Americans take a painkiller regularly, although elders are among the most under treated for pain. Of the community-dwelling elder population, 25 percent to 50 percent can expect to suffer pain. Among institutionalized elders, up to 83 percent report at least one pain problem.
  - The annual cost of **chronic pain** in the United States, including health care expenses, lost income, and lost productivity, is estimated to be \$100 billion.
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## Parkinson's Disease (PD)

- **Parkinson's disease** affects both men and women in almost equal numbers. Today, 1.5 million Americans have PD, and each year 60,000 new cases are diagnosed. While PD usually develops after age 65, 15 percent of those diagnosed are under age 50.<sup>21</sup>
  - It is estimated that **PD** costs the United States over \$26 billion annually in disability costs and lost productivity.<sup>22</sup>
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## Prostate, Enlarged (benign prostatic hyperplasia)<sup>15</sup>

- For men over age 50, the most common prostate problem is **benign prostatic hyperplasia (BPH)**. An estimated 9 million men have BPH symptoms, and each year about 400,000 have surgery to remove some of the enlarged gland that impairs the flow of urine through the urethra.
  - In 2000, **BPH** cost \$1.1 billion annually in direct expenditures for medical services provided at hospital inpatient and outpatient settings, emergency departments, and physicians' offices.
- 

## Rheumatoid Arthritis (RA)<sup>17</sup>

- **RA** affects some 1.3 million Americans. Seventy percent of people with RA are women, but men tend to be more severely affected when they get it.
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## Sepsis<sup>23</sup>

- **Sepsis** caused by infection occurs in approximately one in five of all hospital admissions. More than 700,000 cases of severe sepsis occur in the United States annually.
- Death rates from severe **sepsis** are highly variable, but the overall rate is approximately one-third of all cases. Death rates vary considerably by age, ranging from 5 percent to 35 percent of young people to 37 percent to 50 percent of older people. On average, fewer than one-third of those who suffer an episode of severe sepsis are still alive one year later.
- Every minute of every day, two people die from **sepsis** in the United States. It is the leading cause of death in hospital intensive care units, taking more lives than **breast, colorectal, pancreatic, and prostate cancer** combined.
- By one estimate, **sepsis** is responsible for up to \$10 billion of the annual U.S. health-care budget.

# SELECTED FACTS ABOUT DISEASES AFFECTING AMERICANS AGE 65 AND OLDER

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## Sexual Dysfunction

- Estimates of the number of men who experience **erectile dysfunction (ED)** range from 15 million to 30 million. Up to 25 percent of men at age 65 experience impotence. Diseases—such as **diabetes, kidney disease, atherosclerosis, vascular disease, and neurologic disease**—account for about 70 percent of ED cases.<sup>15</sup>
  - **Female sexual arousal disorder (FASD)** affects up to 25 percent of all American women, or an estimated 47 million women. Three-fourths of women with FASD are postmenopausal.<sup>24</sup>
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## Sleep Disorders

- Some 60 million Americans a year have **insomnia** frequently or for extended periods of time. It affects about 40 percent of women and 30 percent of men.<sup>25</sup> Insomnia is more common among people over the age of 65 than in those ages 18 to 34.<sup>26</sup>
  - Some researchers estimate that **restless legs syndrome (RLS)** affects 12 million Americans, but others estimate a much higher prevalence because RLS is thought to be under diagnosed or misdiagnosed. RLS occurs in both genders, although the incidence may be slightly higher in women. While the syndrome may begin at any age, even in infancy, most people who are severely affected are middle-aged or older, and the severity of the disorder appears to increase with age.<sup>27</sup>
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## Stroke<sup>2</sup>

- About 780,000 Americans will have a **stroke** this year—that's someone every 40 seconds. In adults over age 55, the lifetime risk for stroke is greater than 1 in 6.
  - **Stroke** accounted for about one of every 16 deaths in the United States in 2004. On average, every three to four minutes, someone dies of a stroke. Because women live longer than men, more women than men die of stroke each year. Women accounted for 61 percent of U.S. stroke deaths in 2004.
  - The direct and indirect costs of **stroke** are estimated to be \$65.5 billion in 2008.
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# SELECTED FACTS ABOUT DISEASES AFFECTING AMERICANS AGE 65 AND OLDER

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## THE DRUG DISCOVERY, DEVELOPMENT AND APPROVAL PROCESS

It takes 10-15 years on average for an experimental drug to travel from the lab to U.S. patients. Only five in 5,000 compounds that enter preclinical testing make it to human testing. One of these five tested in people is approved.

Discovery/ Preclinical Testing		Clinical Trials			FDA	Phase IV
Years	6.5	Phase I	Phase II	Phase III	1.5	
Test Population	Laboratory and animal studies	20 to 100 healthy volunteers	100 to 500 patient volunteers	1,000 to 5,000 patient volunteers	Review process/ approval	Additional post- marketing testing required by FDA
Purpose	Assess safety, biological activity and formulations	Determine safety and dosage	Evaluate effectiveness, look for side effects	Confirm effectiveness, monitor adverse reactions from long-term use		
Success Rate	5,000 compounds evaluated	5 enter trials			1 approved	

## THE DRUG DEVELOPMENT AND APPROVAL PROCESS

The U.S. system of new drug approvals is perhaps the most rigorous in the world.

It takes 10-15 years, on average, for an experimental drug to travel from lab to U.S. patients, according to the Tufts Center for the Study of Drug Development, based on drugs approved from 1994 through 1998. Only five in 5,000 compounds that enter preclinical testing make it to human testing. And only one of those five is approved for sale.

On average, it costs a company \$1.3 billion to get one new medicine from the laboratory to U.S. patients, according to a 2007 study by the Tufts Center for the Study of Drug Development.

Once a new compound has been identified in the laboratory, medicines are developed as follows:

**Preclinical Testing.** A pharmaceutical company conducts laboratory and animal studies to show biological activity of the compound against the targeted disease, and the compound is evaluated for safety.

**Investigational New Drug Application (IND).** After completing preclinical testing, a company files an IND with the U.S. Food and Drug Administration (FDA) to begin to test the drug in people. The IND becomes effective if FDA does not disapprove it within 30 days. The IND shows results of previous experiments; how, where and by whom the new studies will be conducted; the chemical structure of the compound; how it is thought to work in the body; any toxic effects found in the animal studies; and how the compound is manufactured. All clinical trials must be reviewed and approved by the Institutional Review Board (IRB) where the trials will be conducted. Progress reports on clinical trials must be submitted at least annually to FDA and the IRB.

**Clinical Trials, Phase I.** These tests involve about 20 to 100 normal, healthy volunteers. The tests study a drug's safety profile, including the safe dosage range. The studies also determine how a drug is absorbed, distributed, metabolized, and excreted as well as the duration of its action.

**Clinical Trials, Phase II.** In this phase, controlled trials of approximately 100 to 500 volunteer patients (people with the disease) assess a drug's effectiveness.

**Clinical Trials, Phase III.** This phase usually involves 1,000 to 5,000 patients in clinics and hospitals. Physicians monitor patients closely to confirm efficacy and identify adverse events.

**New Drug Application (NDA)/Biologic License Application (BLA).** Following the completion of all three phases of clinical trials, a company analyzes all of the data and files an NDA or BLA with FDA if the data successfully demonstrate both safety and effectiveness. The applications contain all of the scientific information that the company has gathered. Applications typically run 100,000 pages or more. The average review time for the 26 new therapeutics approved by the FDA in 2007 was 11.1 months.

**Approval.** Once FDA approves an NDA or BLA, the new medicine becomes available for physicians to prescribe. A company must continue to submit periodic reports to FDA, including any cases of adverse reactions and appropriate quality-control records. For some medicines, FDA requires additional trials (Phase IV) to evaluate long-term effects.

Discovering and developing safe and effective new medicines is a long, difficult, and expensive process. Pharmaceutical companies invested an estimated \$58.8 billion in research and development in 2007.

*Medicines in Development for Older Americans* is presented by PhRMA in cooperation with the following organizations:

American Academy of Allergy, Asthma and Immunology  
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