

# Women

PRESENTED BY AMERICA'S BIOPHARMACEUTICAL RESEARCH COMPANIES

## More Than 800 Medicines Are in Testing for Diseases Disproportionately Affecting American Women

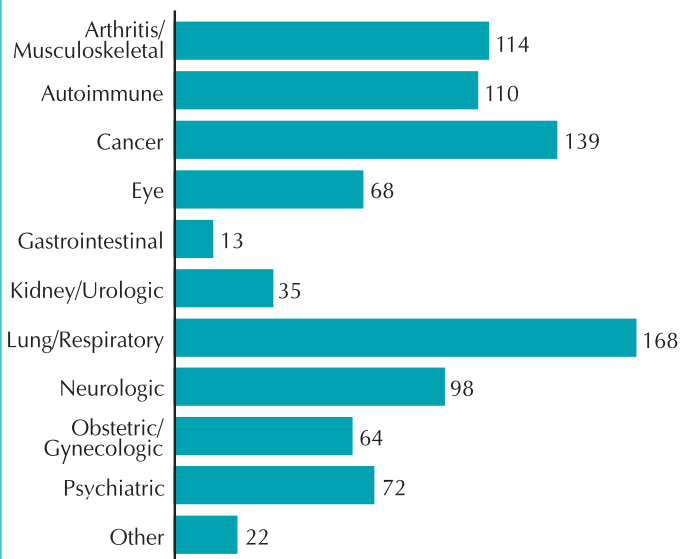
America's pharmaceutical research and biotechnology companies are developing 851 medicines for diseases that disproportionately affect American women. The medicines in the pipeline for women (either in clinical trials or awaiting review by the Food and Drug Administration) include:

- 139 for cancers affecting women, including 91 for breast cancer, 49 for ovarian cancer, and 9 for cervical cancer.
- 114 for arthritis/musculoskeletal disorders. Approximately 46 million Americans have some type of arthritis or related condition, and 60 percent of them are female.
- 64 for obstetric/gynecologic conditions.
- 110 for autoimmune diseases, which strike women three times more than men.
- 72 for depression and anxiety. Almost twice as many women as men suffer from these disorders.
- 83 for Alzheimer's disease. Two-thirds (3.4 million) of the 5.4 million Americans living with Alzheimer's today are women.

Among the potential new medicines in development for women:

- A medicine that uses nanotechnology that targets a cytokine that plays a key role in the inflammatory process associated with rheumatoid arthritis.
- A first-in-class medicine in development for ovarian cancer that induces cell death and reduces cancer growth by inhibiting an enzyme responsible for cell division.
- A first-in-class medicine in development for migraine that selectively blocks transmission of pain signals to the brain.
- A new monoclonal antibody in development for lupus modulates B-cells that produce antibodies against the body's own cells and tissue, causing the immune system to turn on itself.

### MEDICINES AND VACCINES IN DEVELOPMENT FOR WOMEN\*



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

In separate reports, PhRMA has found that researchers are working on 299 medicines for heart disease and stroke—which kill nearly half a million women each year—and 98 medicines for lung cancer, the leading cancer killer of women (see page 60 for details).

America's pharmaceutical research and biotechnology companies continue making exciting progress in the search for new cures and treatments for diseases of special concern to women. We live in an era in which we understand ever more about the difference between the sexes and their health care needs. This knowledge is inspiring a continuing medical revolution that is bringing new hope to women around the world.

John J. Castellani  
President and CEO  
PhRMA

# Medicines in Development for Women

## ARTHRITIS/MUSCULOSKELETAL DISORDERS

Product Name	Company	Indication	Development Status*
ACE-011 (sotatercept)	Acceleron Pharma <i>Cambridge, MA</i> Celgene <i>Summit, NJ</i>	postmenopausal osteoporosis	Phase I (617) 649-9200 (908) 673-9000
<b>Actemra™</b> tocilizumab	Genentech <i>South San Francisco, CA</i>	systemic-onset juvenile idiopathic arthritis	application submitted (800) 626-3553
		early-stage rheumatoid arthritis	Phase III (800) 626-3553
		rheumatoid arthritis (subcutaneous)	Phase III (800) 626-3553
AGN-XX/YY	ACADIA Pharmaceuticals <i>San Diego, CA</i> Allergan <i>Irvine, CA</i>	fibromyalgia (see also gastrointestinal)	Phase II (858) 558-2871 (800) 433-8871
AIN457 (secukinumab)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	rheumatoid arthritis (see also autoimmune)	Phase II (888) 669-6682
alendronate effervescent	Nycomed US <i>Melville, NY</i> EffRx <i>Lausanne, Switzerland</i>	osteoporosis	application submitted (631) 454-7677
AMG 167	Amgen <i>Thousand Oaks, CA</i>	osteopenia	Phase I (800) 772-6436
AMG 785 (anti-sclerostin mAb)	Amgen <i>Thousand Oaks, CA</i>	postmenopausal fracture, postmenopausal osteoporosis	Phase II (800) 772-6436
AMG 827 (mAb)	Amgen <i>Thousand Oaks, CA</i>	rheumatoid arthritis (see lung/respiratory)	Phase II (800) 772-6436
anti-LT alpha (RG-7416)	Genentech <i>South San Francisco, CA</i>	rheumatoid arthritis	Phase II (800) 626-3553
anti-TWEAK (BIIB 023)	Biogen Idec <i>Cambridge, MA</i>	rheumatoid arthritis (see also kidney/urologic)	Phase I (617) 679-2000
<b>Aprala™</b> bazedoxifene/ conjugated estrogens	Ligand Pharmaceuticals <i>San Diego, CA</i> Pfizer <i>New York, NY</i>	postmenopausal osteoporosis prevention (see also obstetric/gynecologic)	Phase III (858) 550-7500 (860) 732-5156
apremilast	Celgene <i>Summit, NJ</i>	rheumatoid arthritis	Phase II (908) 673-9000
<b>Arcoxia™</b> etoricoxib	Merck <i>Whitehouse Station, NJ</i>	rheumatoid arthritis	Phase III (800) 672-6372

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

# ARTHRITIS/MUSCULOSKELETAL DISORDERS

Product Name	Company	Indication	Development Status
ARG301	arGentis <i>Memphis, TN</i>	rheumatoid arthritis	Phase I (901) 818-3262
atripimod	Callisto Pharmaceuticals <i>New York, NY</i>	rheumatoid arthritis	Phase II completed (212) 297-0010
AUS-131	Ausio Pharmaceuticals <i>Cincinnati, OH</i>	osteoporosis (see also obstetric/gynecologic)	Phase I (513) 731-1600
AVL-92	Avila Therapeutics <i>Waltham, MA</i>	rheumatoid arthritis	Phase I (781) 891-0086
BA-058	Radius Health <i>Cambridge, MA</i>	osteoporosis	Phase II (617) 551-4700
BAFF antibody (LY2127399)	Eli Lilly <i>Indianapolis, IN</i>	rheumatoid arthritis (see also autoimmune)	Phase III (800) 545-5979
BG-12 (dimethyl fumarate)	Biogen Idec <i>Cambridge, MA</i>	rheumatoid arthritis (see also autoimmune)	Phase II completed (617) 679-2000
BI 113823	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	osteoarthritis	Phase I (800) 243-0127
BMS-817399 (CCR1 antagonist)	Bristol-Myers Squibb <i>Princeton, NJ</i>	rheumatoid arthritis	Phase I (212) 546-4000
BMS-945429 (anti-IL6)	Bristol-Myers Squibb <i>Princeton, NJ</i> Alder Biopharmaceuticals <i>Bothell, WA</i>	rheumatoid arthritis	Phase I (212) 546-4000 (425) 205-2900
calcitonin oral	Tarsa Therapeutics <i>Philadelphia, PA</i>	postmenopausal osteoporosis treatment	Phase III completed (267) 273-7940
		postmenopausal osteoporosis prevention	Phase II (267) 273-7940
CAM-3001 (anti-GM-CSFR mAb)	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	rheumatoid arthritis	Phase II (800) 236-9933 (301) 398-0000
CCX354	ChemoCentryx <i>Mountain View, CA</i>	rheumatoid arthritis	Phase II (650) 210-2900
cenplacel-L (PDA-001)	Celgene Cellular Therapeutics <i>Summit, NJ</i>	rheumatoid arthritis (see also autoimmune)	Phase I/II (908) 673-9000
CF101	Can-Fite BioPharma <i>Petah-Tikva, Israel</i>	rheumatoid arthritis (see also eye)	Phase II <a href="http://www.canfite.com">www.canfite.com</a>
CG-100649	CG Pharmaceuticals <i>Emeryville, CA</i>	inflammation associated with osteoarthritis	Phase I (510) 594-8200
CH-4051	Chelsea Therapeutics <i>Charlotte, NC</i>	rheumatoid arthritis	Phase II (704) 341-1516
CNTO-136 (sirukumab)	Centocor Ortho Biotech <i>Horsham, PA</i>	rheumatoid arthritis (see also kidney/urologic)	Phase II (610) 651-6000

# ARTHRITIS/MUSCULOSKELETAL DISORDERS

Product Name	Company	Indication	Development Status
DP-001	Deltanoid Pharmaceuticals <i>Madison, WI</i>	osteoporosis	Phase II (608) 238-7710
droxidopa	Chelsea Therapeutics <i>Charlotte, NC</i>	fibromyalgia (see also other)	Phase II (704) 341-1516
EVT 401	Evotec <i>North Potomac, MD</i>	rheumatoid arthritis	Phase I completed (240) 683-1199
fezakinumab (ILV-094)	Pfizer <i>New York, NY</i>	rheumatoid arthritis (see also autoimmune)	Phase II (860) 732-5156
fibroblast growth factor-18	EMD Serono <i>Rockland, MA</i>	osteoarthritis	Phase I (800) 283-8088
flupirtine	Adeona Pharmaceuticals <i>Ann Arbor, MI</i> Meda Pharmaceuticals <i>Somerset, NJ</i>	fibromyalgia	Phase II (734) 332-7800 (732) 564-2200
fostamatinib	AstraZeneca <i>Wilmington, DE</i> Rigel Pharmaceuticals <i>South San Francisco, CA</i>	rheumatoid arthritis	Phase III (800) 236-9933 (650) 624-1100
gevokizumab (XOMA052)	XOMA <i>Berkeley, CA</i>	rheumatoid arthritis (see also autoimmune)	Phase II (510) 204-7200
GSK315234 (oncostatin M mAb)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	rheumatoid arthritis	Phase II (888) 825-5249
GSK768974 (parathyroid hormone receptor agonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Unigene <i>Boonton, NJ</i>	osteoporosis	Phase II (888) 825-5249 (973) 265-1100
HE3286	Hollis-Eden Pharmaceuticals <i>San Diego, CA</i>	rheumatoid arthritis	Phase I/II completed (858) 587-9333
<b>Humira®</b> adalimumab	Abbott Laboratories <i>Abbott Park, IL</i>	early rheumatoid arthritis (see also kidney/urologic)	Phase III (847) 937-6100
IBU-PC	PLx Pharma <i>Houston, TX</i>	pain and inflammation associated with osteoarthritis	Phase II (713) 842-1249
IL-17 antibody (LY2439821)	Eli Lilly <i>Indianapolis, IN</i>	rheumatoid arthritis	Phase II (800) 545-5979
<b>Ilaris®</b> canakinumab	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	systemic juvenile idiopathic arthritis (subcutaneous) (see also autoimmune, lung/respiratory)	Phase III (888) 669-6682
		osteoarthritis (intra-arterial)	Phase II (888) 669-6682
IR-raloxifene	SCLOR Pharma <i>Bothell, WA</i>	osteoporosis	Phase I completed (425) 368-1050
JAK-1/JAK-2 (LY3009104)	Eli Lilly <i>Indianapolis, IN</i>	rheumatoid arthritis	Phase II (800) 545-5979

# ARTHRITIS/MUSCULOSKELETAL DISORDERS

Product Name	Company	Indication	Development Status
JNJ-40346527	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	rheumatoid arthritis	Phase I (800) 817-5286
JZP-6 (sodium oxybate)	Jazz Pharmaceuticals <i>Palo Alto, CA</i>	fibromyalgia	application submitted (650) 496-3777
		fibromyalgia (in combination with oral solution)	Phase III (650) 496-3777
KB002/003 (anti-GM-CSF)	KaloBios Pharmaceuticals <i>South San Francisco, CA</i>	rheumatoid arthritis	Phase II (650) 243-3100
<b>Lodotra®</b> prednisone controlled-release	Horizon Pharma <i>Northbrook, IL</i>	rheumatoid arthritis (see also autoimmune)	Phase III completed (224) 383-3000
LT-NS001 (naproxen etemesil)	Logical Therapeutics <i>Waltham, MA</i>	osteoarthritis	Phase II/III (781) 290-0900
LX2931	Lexicon Pharmaceuticals <i>The Woodlands, TX</i>	rheumatoid arthritis	Phase II (281) 863-3000
<b>Lyrica® CR</b> pregabalin (controlled-release)	Pfizer <i>New York, NY</i>	fibromyalgia (see also psychiatric)	Phase II/III (860) 723-5156
MAXY-4 (CTLA4-Ig fusion protein)	Astellas Pharma US <i>Deerfield, IL</i> Perseid Therapeutics <i>Redwood City, CA</i>	rheumatoid arthritis	Phase I (800) 695-4321 (650) 298-5800
MEDI-578 (anti-NGF mAb)	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	osteoarthritic pain	Phase I (800) 236-9933 (301) 298-0000
MER-103	Merrion Pharmaceuticals <i>Wilmington, DE</i>	osteoporosis	Phase II completed (910) 799-1847
MK-5442	Merck <i>Whitehouse Station, NJ</i>	osteoporosis	Phase II (800) 672-6372
naproxcinod	NicOx <i>Sophia Antipolis, France</i>	osteoarthritis	application submitted www.nicox.com
<b>Neupro®</b> rotigotine transdermal	UCB <i>Smyrna, GA</i>	fibromyalgia	Phase II (770) 970-7500
NN8209 (anti-C5aR mAb)	Novo Nordisk <i>Princeton, NJ</i>	rheumatoid arthritis	Phase II (609) 987-5800
NN8226 (anti-IL-20 antibody)	Novo Nordisk <i>Princeton, NJ</i>	rheumatoid arthritis	Phase II (609) 987-5800
NN8555 (mAb)	Novo Nordisk <i>Princeton, NJ</i>	rheumatoid arthritis	Phase II (609) 987-5800
NN8828 (anti-IL-21 mAb)	Novo Nordisk <i>Princeton, NJ</i>	rheumatoid arthritis	Phase I (609) 987-5800

# ARTHRITIS/MUSCULOSKELETAL DISORDERS

Product Name	Company	Indication	Development Status
NU3450	Nuon Therapeutics <i>San Mateo, CA</i>	rheumatoid arthritis	Phase II (650) 645-1800
odanacatib (MK-0822)	Merck <i>Whitehouse Station, NJ</i>	postmenopausal osteoporosis	Phase III (800) 672-6372
ofatumumab (HuMax-CD20)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	rheumatoid arthritis (intravenous) (see also autoimmune)	Phase II (888) 825-5249
		rheumatoid arthritis (subcutaneous)	Phase II (888) 825-5249
olokizumab	UCB <i>Smyrna, GA</i>	rheumatoid arthritis	Phase II (770) 970-7500
<b>Oralgam™</b> oral human gammaglobulin <b>(Orphan Drug)</b>	Latona Life Sciences <i>Phoenix, AZ</i>	juvenile rheumatoid arthritis, rheumatoid arthritis	Phase II completed (480) 254-8530
<b>Orencia®</b> abatacept (subcutaneous)	Bristol-Myers Squibb <i>Princeton, NJ</i>	moderate to severe rheumatoid arthritis (see also autoimmune, kidney/urologic)	application submitted (212) 546-4000
		early-stage rheumatoid arthritis	Phase III (212) 546-4000
osteoarthritis compound	Eli Lilly <i>Indianapolis, IN</i>	osteoarthritis	Phase I (800) 545-5979
osteoporosis compound (LY2541546)	Eli Lilly <i>Indianapolis, IN</i>	osteoporosis	Phase II (800) 545-5979
otelixizumab	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Tolerx <i>Cambridge, MA</i>	rheumatoid arthritis (see also autoimmune)	Phase II (888) 825-5249 (617) 354-8100
ozoralizumab (ATN-103)	Pfizer <i>New York, NY</i>	rheumatoid arthritis	Phase II (860) 732-5156
PF-04171327	Pfizer <i>New York, NY</i>	rheumatoid arthritis	Phase II (860) 732-5156
PF-04236921	Pfizer <i>New York, NY</i>	rheumatoid arthritis (see also autoimmune)	Phase I (860) 732-5156
PF-05230905 (ATN-192)	Pfizer <i>New York, NY</i>	rheumatoid arthritis	Phase I (860) 732-5156
PLX3397	Plexxikon <i>Berkeley, CA</i>	rheumatoid arthritis	Phase I (510) 647-4000
PLX5622	Plexxikon <i>Berkeley, CA</i>	rheumatoid arthritis	Phase I (510) 647-4000
PMI-001	Phytomedics <i>Jamesburg, NJ</i>	rheumatoid arthritis	Phase II completed (609) 655-0715

# ARTHRITIS/MUSCULOSKELETAL DISORDERS

Product Name	Company	Indication	Development Status
PRO-515	Cypress Bioscience <i>San Diego, CA</i>	rheumatoid arthritis	Phase II (858) 452-2323
PRTX-100	Protalex <i>New Hope, PA</i>	rheumatoid arthritis (see also autoimmune)	Phase I (215) 862-9720
<b>Reclast®</b> zoledronic acid	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	corticosteroid-induced osteoporosis, postmenopausal osteoporosis prevention	application submitted (888) 669-6682
RG4934 (anti-IL-17 mAb)	Roche <i>Nutley, NJ</i>	rheumatoid arthritis	Phase II (973) 235-5000
RPI-78	ReceptoPharm <i>Plantation, FL</i>	rheumatoid arthritis	Phase I (954) 321-8988
RX-10001	Resolvix Pharmaceuticals <i>Cambridge, MA</i>	rheumatoid arthritis (see also lung/respiratory)	Phase I (781) 541-5045
SAN-300 (anti-VLA-1 antibody)	Santarus <i>San Diego, CA</i>	rheumatoid arthritis	Phase I (858) 314-5700
SAR113945 (IKK- $\beta$ inhibitor)	sanofi-aventis <i>Bridgewater, NJ</i>	osteoarthritis	Phase I (800) 633-1610
SAR114137 (cathepsin S/K inhibitor)	sanofi-aventis <i>Bridgewater, NJ</i>	osteoarthritic pain	Phase I (800) 633-1810
SAR153191 (anti-IL-6R mAb)	Regeneron Pharmaceuticals <i>Tarrytown, NY</i> sanofi-aventis <i>Bridgewater, NJ</i>	rheumatoid arthritis	Phase II (914) 345-7400 (800) 633-1610
SAR292833 (GRC15300) TRPV3 antagonist	sanofi-aventis <i>Bridgewater, NJ</i> Glenmark Pharmaceuticals <i>Mumbai, India</i>	osteoarthritic pain	Phase I (800) 633-1810
SBI-087 (PF-05230895)	Emergent BioSolutions <i>Rockville, MD</i> Pfizer <i>New York, NY</i>	rheumatoid arthritis (see also autoimmune)	Phase II (301) 795-1800 (860) 732-5156
SCH-900117	Merck <i>Whitehouse Station, NJ</i>	rheumatoid arthritis	Phase I (800) 672-6372
SD-6010	Pfizer <i>New York, NY</i>	osteoarthritis	Phase II/III (860) 732-5156
<b>Simponi™</b> golimumab	Centocor Ortho Biotech <i>Horsham, PA</i>	rheumatoid arthritis (intravenous)	Phase III (610) 651-6000
		juvenile rheumatoid arthritis (subcutaneous)	Phase III (610) 651-6000
SMC021 (calcitonin oral)	Emisphere Technologies <i>Tarrytown, NY</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	osteoarthritis, postmenopausal osteoporosis	Phase III (914) 347-2220 (888) 669-6682



# ARTHRITIS/MUSCULOSKELETAL DISORDERS

Product Name	Company	Indication	Development Status
<b>Synavive™</b> prednisone/ dipyridamole	Zalicus <i>Cambridge, MA</i>	osteoarthritis, rheumatoid arthritis	Phase II completed (617) 301-7000
T-5224	Toyama Chemical <i>Tokyo, Japan</i>	rheumatoid arthritis	Phase I
teriparatide intranasal	Marina Biotech <i>Bothell, WA</i>	osteoporosis	Phase II (425) 908-3600
teriparatide oral (PTH134)	Emisphere Technologies <i>Tarrytown, NY</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	postmenopausal osteoporosis	Phase I (914) 347-2220 (888) 669-6682
teriparatide transdermal (ZP-PTH)	Zosana Pharma <i>Fremont, CA</i>	osteoporosis	Phase II (510) 745-1200
TG-C	TissueGene <i>Rockville, MD</i>	osteoarthritis	Phase I (301) 921-6000
TNX-102	TONIX Pharmaceuticals <i>New York, NY</i>	fibromyalgia syndrome	Phase II (212) 980-9155
tofacitinib	Pfizer <i>New York, NY</i>	rheumatoid arthritis	Phase III (860) 732-5156
<b>Veldona®</b> interferon-alpha lozenge	Amarillo Biosciences <i>Amarillo, TX</i>	fibromyalgia (see also lung/respiratory, obstetric/gynecologic)	Phase II (806) 376-1741
veltuzumab	Immunomedics <i>Morris Plains, NJ</i>	rheumatoid arthritis (see also autoimmune)	Phase II (973) 605-8200
VGX™-1027	Inovio Pharmaceuticals <i>Blue Bell, PA</i>	rheumatoid arthritis (see also autoimmune)	Phase I completed (267) 440-4200
ViaDor-hPTH (1-34) (teriparatide transdermal)	Eli Lilly <i>Indianapolis, IN</i> TransPharma Medical <i>Lod, Israel</i>	osteoporosis	Phase I (800) 545-5979
<b>Vimpat®</b> lacosamide	UCB <i>Smyrna, GA</i>	fibromyalgia	Phase II completed (770) 970-7500
<b>Viviant™</b> bazedoxifene	Ligand Pharmaceuticals <i>San Diego, CA</i> Pfizer <i>New York, NY</i>	postmenopausal osteoporosis prevention and treatment	application submitted (858) 550-7500 (860) 732-5156
VX-509	Vertex Pharmaceuticals <i>Cambridge, MA</i>	rheumatoid arthritis	Phase II (877) 634-8789
<b>Xgeva™</b> denosumab	Amgen <i>Thousand Oaks, CA</i>	treatment-induced bone loss in patients with breast cancer	application submitted (800) 772-6436
		rheumatoid arthritis	Phase II completed (800) 772-6436



## ARTHRITIS/MUSCULOSKELETAL DISORDERS

Product Name	Company	Indication	Development Status
ZT-034 (teriparatide)	Zelos Therapeutics <i>West Conshohocken, PA</i>	osteoporosis (intranasal)	Phase I (610) 260-6045
		osteoporosis (subcutaneous)	Phase I (610) 260-6045

## AUTOIMMUNE DISEASES

Product Name	Company	Indication	Development Status
<i>Medicines in development for rheumatoid arthritis are listed under Arthritis/Musculoskeletal Disorders.</i>			
A-623	Anthera Pharmaceuticals <i>Hayward, CA</i>	systemic lupus erythematosus	Phase II (510) 856-5600
<b>Afrezza®</b> insulin inhalation	MannKind <i>Valencia, CA</i>	type 1 diabetes	application submitted (661) 775-5300
AGS-009	Argos Therapeutics <i>Durham, NC</i>	systemic lupus erythematosus	Phase I (919) 287-6300
AIN457 (secukinumab)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	multiple sclerosis (see also arthritis/musculoskeletal)	Phase II (888) 669-6682
alpha-1-antitrypsin (AAT)	Omni Bio Pharmaceutical <i>Greenwood Village, CO</i>	type 1 diabetes	Phase I/II (303) 867-3415
AMG 557	Amgen <i>Thousand Oaks, CA</i>	systemic lupus erythematosus	Phase I (800) 772-6436
AMG 811	Amgen <i>Thousand Oaks, CA</i>	discoid lupus erythematosus, systemic lupus erythematosus	Phase I (800) 772-6436
ARG201 <b>(Orphan Drug)</b>	arGentis Pharmaceuticals <i>Memphis, TN</i>	systemic scleroderma	Phase II (901) 552-4730
ARX424 (PEGylated interferon beta-1a)	Ambrx <i>La Jolla, CA</i> EMD Serono <i>Rockland, MA</i>	multiple sclerosis	Phase I (858) 875-2400 (800) 298-8088
AT1391 (daily insulin skin patch)	Altea Therapeutics <i>Atlanta, GA</i>	type 1 diabetes	Phase I/II (404) 835-6310
atacept (TACI-Ig)	EMD Serono <i>Rockland, MA</i>	systemic lupus erythematosus	Phase III (800) 283-8088
autoimmune diabetes vaccine	Diamyd <i>Pittsburgh, PA</i>	type 1 diabetes	Phase III (412) 488-0348
AZD1656	AstraZeneca <i>Wilmington, DE</i>	type 1 diabetes	Phase II (800) 236-9933
BAF312	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	multiple sclerosis	Phase II (888) 669-6682
BAFF antibody (LY2127399)	Eli Lilly <i>Indianapolis, IN</i>	systemic lupus erythematosus (see also arthritis/musculoskeletal)	Phase III (800) 545-5979
		multiple sclerosis	Phase II (800) 545-5979

## AUTOIMMUNE DISEASES

Product Name	Company	Indication	Development Status
baminercept (BG9924)	Biogen Idec <i>Cambridge, MA</i>	multiple sclerosis	Phase I/II (617) 679-2000
basal insulin (LY2605541)	Boehringer Ingelheim <i>Ridgefield, CT</i> Eli Lilly <i>Indianapolis, IN</i>	type 1 diabetes	Phase II (800) 243-0127 (800) 545-5979
BAY 85-8101	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	multiple sclerosis diagnosis (see also neurologic)	Phase I completed (888) 842-2937
<b>Benlysta®</b> belimumab (subcutaneous)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Human Genome Sciences <i>Rockville, MD</i>	systemic lupus erythematosus	Phase II (888) 825-5249 (301) 309-8504
BG-12 (dimethyl fumarate)	Biogen Idec <i>Cambridge, MA</i>	multiple sclerosis (Fast Track) (see also arthritis/musculoskeletal)	Phase III (617) 679-2000
BHT-3009	Bayhill Therapeutics <i>Palo Alto, CA</i>	multiple sclerosis	Phase II completed (650) 320-2800
BHT-3201 (RG7426)	Bayhill Therapeutics <i>Palo Alto, CA</i> Genentech <i>South San Francisco, CA</i>	type 1 diabetes	Phase I (650) 320-2800 (800) 626-3553
BIIB 017 (PEG-interferon beta-1a)	Biogen Idec <i>Cambridge, MA</i>	relapsing multiple sclerosis (Fast Track)	Phase III (617) 679-2000
BIIB 033 (anti-LINGO)	Biogen Idec <i>Cambridge, MA</i>	multiple sclerosis	Phase I (617) 679-2000
BIOD-102	Biodel <i>Danbury, CT</i>	type 1 diabetes	Phase I (203) 796-5000
<b>Campath®</b> alemtuzumab	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> Genzyme <i>Cambridge, MA</i>	relapsing-remitting multiple sclerosis (Fast Track)	Phase III (888) 842-2937 (617) 252-7500
CC-10015	Celgene <i>Summit, NJ</i>	systemic scleroderma	Phase I (908) 673-9000
CC-11050	Celgene <i>Summit, NJ</i>	cutaneous lupus erythematosus	Phase II (908) 673-9000
CCX168	ChemoCentryx <i>Mountain View, CA</i>	autoimmune disorders	Phase I (650) 210-2900
CDP-7657 (CD40L)	Biogen Idec <i>Cambridge, MA</i>	systemic lupus erythematosus	Phase I (617) 679-2000
<b>CellCept®</b> mycophenolate mofetil (Orphan Drug)	Aspreva Pharmaceuticals <i>Basking Ridge, NJ</i>	pemphigus vulgaris (see also kidney/urologic)	Phase III completed (908) 212-1020

## AUTOIMMUNE DISEASES

Product Name	Company	Indication	Development Status
cenplacel-L (PDA-001)	Celgene Cellular Therapeutics <i>Summit, NJ</i>	multiple sclerosis (see also arthritis/musculoskeletal)	Phase I/II (908) 673-9000
CK-2017357	Cytokinetix <i>South San Francisco, CA</i>	myasthenia gravis	Phase II (650) 624-3000
<b>Copaxone®</b> glatiramer	Teva Neuroscience <i>North Wales, PA</i>	multiple sclerosis (low volume formulation, 20mg)	application submitted (800) 838-2872
		multiple sclerosis (40mg)	Phase III (800) 838-2872
CS-0777	Daiichi Sankyo <i>Parsippany, NJ</i>	multiple sclerosis	Phase I completed (973) 944-2600
<b>DiaPep 277®</b>	Andromeda Biotech <i>Yavne, Israel</i> Teva Pharmaceuticals USA <i>North Wales, PA</i>	type 1 diabetes	Phase III (215) 591-3000
E5501	Eisai <i>Woodcliff Lake, NJ</i>	idiopathic thrombocytopenia purpura	Phase II (888) 422-4743
ELND002	Biogen Idec <i>Cambridge, MA</i> Elan <i>Dublin, Ireland</i>	secondary, progressive multiple sclerosis	Phase I (617) 679-2000
epratuzumab	Immunomedics <i>Morris Plains, NJ</i> UCB <i>Smyrna, GA</i>	systemic lupus erythematosus (Fast Track)	Phase III (973) 605-8200
estriol	Adeona Pharmaceuticals <i>Ann Arbor, MI</i>	multiple sclerosis	Phase II (734) 332-7800
fezakinumab (ILV-094)	Pfizer <i>New York, NY</i>	psoriasis (see also arthritis/musculoskeletal)	Phase III completed (860) 732-5156
firategrast	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	multiple sclerosis	Phase II (888) 825-5249
forigerimod (CEP-33457)	Cephalon <i>Frazer, PA</i>	systemic lupus erythematosus	Phase III (610) 344-0200
FX002	Flexion Therapeutics <i>Woburn, MA</i>	autoimmune disorders	Phase II (781) 897-9977
GBR-500	Glenmark Pharmaceuticals <i>Mumbai, India</i>	multiple sclerosis	Phase I
gevokizumab (XOMA052)	XOMA <i>Berkeley, CA</i>	type 1 diabetes (see also arthritis/musculoskeletal)	Phase II (510) 204-7200
<b>Gleevec®</b> imatinib	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	scleroderma	Phase II completed (888) 669-6682
GSK1223249 (NOGO-A mAb)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	multiple sclerosis	Phase I (888) 825-5249

## AUTOIMMUNE DISEASES

Product Name	Company	Indication	Development Status
GSK2018682 (sphingosine-1 phosphate receptor-1)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	multiple sclerosis	Phase I (888) 825-5249
HuCAL-derived antibody	Centocor Ortho Biotech <i>Horsham, PA</i>	autoimmune disorders	Phase I (610) 651-6000
<b>Ilaris®</b> canakinumab	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	type 1 diabetes (see also arthritis/musculoskeletal, lung/respiratory)	Phase II (888) 669-6682
IMO-3100	Idera Pharmaceuticals <i>Cambridge, MA</i>	autoimmune disorders	Phase I competed (617) 679-5500
INGAP peptide	Exsulin <i>Minneapolis, MN</i>	type 1 diabetes	Phase II <a href="http://www.exsulin.com">www.exsulin.com</a>
insulin oral	Generex Biotechnology <i>Toronto, Canada</i>	type 1 diabetes	Phase III (416) 364-2551
insulin transdermal	Dermisonics <i>Irvine, CA</i>	type 1 diabetes	Phase I (888) 401-3376
interferon beta-1a extended-release	EMD Serono <i>Rockland, MA</i>	multiple sclerosis	Phase I (800) 298-8088
<b>Januvia®</b> sildenafil	Merck <i>Whitehouse Station, NJ</i>	type 1 diabetes	Phase III (800) 672-6372
JNK CC-930	Celgene <i>Summit, NJ</i>	discoid lupus erythematosus	Phase II (908) 673-9000
KRP203	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	autoimmune disorders	Phase I (888) 669-6682
laquinimod	Teva Neuroscience <i>North Wales, PA</i>	multiple sclerosis (Fast Track)	Phase III (800) 838-2872
		systemic lupus erythematosus	Phase II (800) 838-2872
<b>Leustatin®</b> cladribine (oral)	EMD Serono <i>Rockland, MA</i>	relapsing-remitting multiple sclerosis (Fast Track)	application submitted (800) 283-8088
		multiple sclerosis (early-stage disease; clinically isolated syndrome)	Phase III (800) 283-8088
lisofylline	DiaKine Therapeutics <i>Charlottesville, VA</i>	type 1 diabetes	Phase I (434) 975-2001
<b>Lodotra®</b> prednisone controlled-release	Horizon Pharma <i>Northbrook, IL</i>	polymyalgia rheumatica (see also arthritis/musculoskeletal)	Phase I completed (224) 383-3000
MEDI-545 (anti-IFN-alpha mAb)	AstraZeneca <i>Wilmington, DE</i> Medarex <i>Princeton, NJ</i> MedImmune <i>Gaithersburg, MD</i>	systemic lupus erythematosus	Phase II (800) 236-9933 (609) 430-2880 (301) 298-0000

## AUTOIMMUNE DISEASES

Product Name	Company	Indication	Development Status
MEDI-546 (anti-IFNalphaR mAb)	AstraZeneca <i>Wilmington, DE</i> Medarex <i>Princeton, NJ</i> MedImmune <i>Gaithersburg, MD</i>	scleroderma	Phase I (800) 236-9933 (301) 298-0000
MEDI-551 (anti-CD19 mAb)	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	scleroderma	Phase I (800) 236-9933 (301) 298-0000
MEDI-570 (anti-ICOS mAb)	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	systemic lupus erythematosus	Phase I (301) 298-0000
metreleptin	Amylin Pharmaceuticals <i>San Diego, CA</i>	type 1 diabetes (see also obstetric/gynecologic)	Phase I (858) 552-2200
nitroglycerin topical	MediQuest Therapeutics <i>Bothell, WA</i>	Raynaud's disease	Phase III (425) 398-9580
NN1218	Novo Nordisk <i>Princeton, NJ</i>	type 1 diabetes	Phase I (800) 727-6500
NN1250 (insulin degludec)	Novo Nordisk <i>Princeton, NJ</i>	type 1 diabetes	Phase III (800) 727-6500
NN1952	Novo Nordisk <i>Princeton, NJ</i>	type 1 diabetes	Phase I (800) 727-6500
NN5401 (insulin degludec/ insulin aspart)	Novo Nordisk <i>Princeton, NJ</i>	type 1 diabetes	Phase III (800) 727-6500
NU100 (interferon beta-1b)	Nuron Biotech <i>Exton, PA</i>	multiple sclerosis	Phase I (610) 968-6650
ocrelizumab (anti-CD20 mAb)	Biogen Idec <i>Cambridge, MA</i> Genentech <i>South San Francisco, CA</i>	primary progressive multiple sclerosis  relapsing-remitting multiple sclerosis	Phase III (617) 679-2000 (800) 626-3553  Phase II (617) 679-2000 (800) 626-3553
ofatumumab (HuMax-CD20)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	multiple sclerosis (see also arthritis/musculoskeletal)	Phase II (888) 825-5249
ONO-4641	Ono Pharma USA <i>Lawrenceville, NJ</i>	multiple sclerosis	Phase II
<b>Orencia®</b> abatacept (intravenous)	Bristol-Myers Squibb <i>Princeton, NJ</i>	systemic lupus erythematosus (see also arthritis/musculoskeletal, kidney/urologic)	Phase II/III (212) 546-4000

## AUTOIMMUNE DISEASES

Product Name	Company	Indication	Development Status
otelixizumab	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Tolerx <i>Cambridge, MA</i>	myasthenia gravis (see also arthritis/musculoskeletal)	Phase II (888) 825-5249 (617) 354-8100
		Grave's eye disease, type 1 diabetes	Phase I (888) 825-5249 (617) 354-8100
PEG-encapsulated islet cell transplantation therapy	Novocell <i>San Diego, CA</i> Pfizer <i>New York, NY</i>	type 1 diabetes	Phase I/II (858) 455-3708 (860) 732-5156
peginterferon beta (AZ01)	Allozyne <i>Seattle, WA</i>	multiple sclerosis	Phase I (206) 518-5700
PF-0489791	Pfizer <i>New York, NY</i>	Raynaud's disease	Phase II (860) 732-5156
PF-04236921	Pfizer <i>New York, NY</i>	lupus vulgaris (see also arthritis/musculoskeletal)	Phase I (860) 732-5156
ponesimod	Actelion Pharmaceuticals US <i>South San Francisco, CA</i>	multiple sclerosis	Phase II (650) 624-6900
<b>Prochymal™</b> remestemcel-L	Osiris Therapeutics <i>Columbia, MD</i>	type 1 diabetes (see also lung/respiratory)	Phase II (443) 545-1800
PRTX-100	Protalex <i>New Hope, PA</i>	autoimmune disorders (see also arthritis/musculoskeletal)	Phase I (215) 862-9720
RG7415 (rontalizumab)	Genentech <i>South San Francisco, CA</i>	systemic lupus erythematosus	Phase II (800) 626-3553
RGN-352 injectable	RegeneRx Biopharmaceuticals <i>Rockville, MD</i>	multiple sclerosis	Phase I (301) 208-9191
rHuPH20 (recombinant human hyaluronidase/insulin)	Halozyne <i>San Diego, CA</i>	type 1 diabetes	Phase II (858) 794-8889
<b>Rituxan®</b> rituximab	Biogen Idec <i>Cambridge, MA</i> Genentech <i>South San Francisco, CA</i>	dermatomyositis, immune thrombocytopenic purpura	Phase II (617) 679-2000 (800) 626-3553
RPC-1063	Receptos <i>San Diego, CA</i>	multiple sclerosis	Phase I (858) 652-5700
RPI-78M	ReceptoPharm <i>Plantation, FL</i>	multiple sclerosis	Phase I completed (954) 321-8988
RTL-1000 (Orphan Drug)	Artielle Immuno Therapeutics <i>Tigard, OR</i>	multiple sclerosis	Phase I (503) 626-1144

## AUTOIMMUNE DISEASES

Product Name	Company	Indication	Development Status
SBI-087 (PF-05230895)	Emergent BioSolutions Rockville, MD Pfizer New York, NY	systemic lupus erythematosus (see also arthritis/musculoskeletal)	Phase I (301) 795-1800 (860) 732-5156
semapimod	Cytokine PharmaSciences King of Prussia, PA	autoimmune disorders	Phase I (610) 687-1776
SLX-2101	Surface Logix Brighton, MA	Raynaud's disease	Phase II (617) 746-8500
<b>Soliris®</b> eculizumab (Orphan Drug)	Alexion Pharmaceuticals Cheshire, CT	antiphospholipid syndrome, autoimmune hemolytic anemia, myasthenia gravis (see also eye)	Phase II (203) 272-2596
<b>Sprycel®</b> dasatinib	Bristol-Myers Squibb Princeton, NJ	scleroderma (see also cancer)	Phase I/II (212) 546-4000
teplizumab (Orphan Drug)	MacroGenics Rockville, MD	type 1 diabetes	Phase III (301) 251-5172
teriflunomide	sanofi-aventis Bridgewater, NJ	multiple sclerosis	Phase III (800) 633-1610
<b>Thymoglobulin®</b> antithymocyte globulin	Genzyme Cambridge, MA	type 1 diabetes	Phase I/II (617) 252-7500
<b>Tovaxin™</b> T-cell therapeutic vaccine	Opexa Therapeutics The Woodlands, TX	multiple sclerosis	Phase II completed (281) 272-9331
treprostinil	United Therapeutics Silver Spring, MD	systemic scleroderma	Phase II (301) 608-9292
TRX1 (anti-CD4 mAb)	TolerRx Cambridge, MA	cutaneous lupus erythematosus	Phase I completed (617) 354-8100
<b>Tysabri®</b> natalizumab	Biogen Idec Cambridge, MA	multiple sclerosis (subcutaneous)	Phase I (617) 679-2000
		multiple sclerosis (intramuscular)	Phase I (617) 679-2000
VBY-29	ViroBay Menlo Park, CA	autoimmune disorders	Phase I (650) 833-5700
veltuzumab	Immunomedics Morris Plains, NJ	immune thrombocytopenic purpura (see also arthritis/musculoskeletal)	Phase I/II (973) 605-8200
VGX™-1027	Inovio Pharmaceuticals Blue Bell, PA	type 1 diabetes (see also arthritis/musculoskeletal)	Phase I completed (267) 440-4200
<b>VIAtab™</b> insulin oral sublingual	Biodel Danbury, CT	type 1 diabetes	Phase I (203) 796-5000
<b>Zenapax®</b> daclizumab (subcutaneous)	Biogen Idec Cambridge, MA	multiple sclerosis – relapsing forms	Phase III (617) 679-2000



# CANCER

Product Name	Company	Indication	Development Status
18F-fluorothymidine	Merck <i>Whitehouse Station, NJ</i>	diagnosis of breast cancer	Phase II (800) 672-6372
Å6	Angstrom Pharmaceuticals <i>Solana Beach, CA</i>	ovarian cancer, advanced gynecological cancer	Phase II (858) 314-2356
abagovomab (anti-idiotypic ovarian cancer vaccine) <b>(Orphan Drug)</b>	Menarini <i>Florence, Italy</i>	ovarian cancer	Phase II/III www.menarini.com
abiraterone acetate (CB7630)	Cougar Biotechnology <i>Raritan, NJ</i>	breast cancer	Phase I/II (800) 817-5286
<b>Abraxane®</b> albumin-bound paclitaxel	Celgene <i>Summit, NJ</i>	ovarian cancer	Phase II (908) 673-9000
ABT-869 (linifarib)	Abbott Laboratories <i>Abbott Park, IL</i>	breast cancer	Phase II (847) 937-6100
ABT-888 (veliparib)	Abbott Laboratories <i>Abbott Park, IL</i>	breast cancer, fallopian tube cancer, ovarian cancer	Phase II (847) 937-6100
acolbifene	EndoCeutics <i>Quebec City, Canada</i>	prevention of breast cancer	Phase II (418) 653-0033
aderbasib (INCB7839)	Incyte <i>Wilmington, DE</i>	breast cancer	Phase II (302) 498-6700
ADXS-11001	Advaxis <i>North Brunswick, NJ</i>	cervical intraepithelial neoplasia	Phase II (732) 545-1590
AE-37	Antigen Express <i>Worcester, MA</i>	breast cancer, ovarian cancer	Phase II (508) 852-8783
afimoxifene	ASCEND Therapeutics <i>Herndon, VA</i>	breast cancer prevention (see also obstetric/gynecologic)	Phase II (703) 471-4744
<b>Afinitor®</b> everolimus	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	breast cancer	Phase III (888) 669-6682
AMG 386	Amgen <i>Thousand Oaks, CA</i>	ovarian cancer	Phase III (800) 772-6436
		breast cancer, fallopian tube cancer	Phase II (800) 772-6436
AMG 479 (ganitumab)	Amgen <i>Thousand Oaks, CA</i>	breast cancer	Phase II (800) 772-6436
anti-CD3 anti-HER/neu activated T-cells	TransTarget <i>Hillsborough, CA</i>	metastatic breast cancer	Phase II
ARRY-380	Array BioPharma <i>Boulder, CO</i>	breast cancer	Phase I (303) 381-6600
AUY922	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	breast cancer	Phase II (888) 669-6682
AV-951 (tivozanib)	AVEO Pharmaceuticals <i>Cambridge, MA</i>	breast cancer	Phase I/II (617) 299-5000

# CANCER

Product Name	Company	Indication	Development Status
<b>Avastin®</b> bevacizumab	Genentech <i>South San Francisco, CA</i>	first-line metastatic breast cancer (with <b>Xeloda®</b> )	Phase III (650) 225-1000
		HER2-positive breast cancer (adjuvant therapy), triple-negative breast cancer (adjuvant therapy), HER2-negative breast cancer (adjuvant therapy)	Phase III (650) 225-1000
		first-line HER2-positive metastatic breast cancer (with <b>Herceptin®</b> )	Phase III (650) 225-1000
		first-line metastatic ovarian cancer, recurrent platinum-sensitive ovarian cancer	Phase III (650) 225-1000
AZD8931 (erbB kinase inhibitor)	AstraZeneca <i>Wilmington, DE</i>	breast cancer	Phase II (800) 236-9933
BC-819	BioCancell Therapeutics <i>Jerusalem, Israel</i>	ovarian cancer	Phase I/II <a href="http://www.biocancell.com">www.biocancell.com</a>
BIBW 2992 (afatinib)	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	metastatic breast cancer	Phase III (800) 243-0127
BKM120	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	breast cancer	Phase I/II (888) 669-6682
BMS-690514 (HER/VEGFR2 inhibitor)	Bristol-Myers Squibb <i>Princeton, NJ</i>	metastatic breast cancer	Phase II (212) 546-4000
BMS-754807 (IGF-1R antagonist)	Bristol-Myers Squibb <i>Princeton, NJ</i>	breast cancer	Phase II (212) 546-4000
breast cancer vaccine	Quantum Immunologics <i>Tampa, FL</i>	breast cancer	Phase I/II (866) 213-4594
BTSCAN	Molecular Targeting Technologies <i>West Chester, PA</i>	diagnosis of breast cancer	Phase I (610) 738-7938
BZL-101	Bionovo <i>Emeryville, CA</i>	breast cancer	Phase I (510) 601-2000
catumaxomab	Fresenius Biotech North America <i>Waltham, MA</i>	ovarian cancer	Phase II <a href="http://www.fresenius-biotech.com">www.fresenius-biotech.com</a>
CDX-011	CellDex Therapeutics <i>Needham, MA</i>	breast cancer (Fast Track)	Phase II (781) 433-0771
CNF-2024	Biogen Idec <i>Weston, MA</i>	breast cancer	Phase II (781) 464-2000

# CANCER

Product Name	Company	Indication	Development Status
<b>CVax™</b> MUC-2 cancer vaccine	Prima BioMed <i>Armadale, Australia</i>	ovarian cancer	Phase II www.prima biomed.com.au
dalotuzumab	Merck <i>Whitehouse Station, NJ</i>	breast cancer	Phase I/II (800) 672-6372
<b>DCVax®-L</b> ovarian cancer vaccine	Northwest Biotherapeutics <i>Bothell, WA</i>	ovarian cancer	Phase I/II (425) 608-3000
dinaciclib	Merck <i>Whitehouse Station, NJ</i>	breast cancer	Phase II (800) 672-6372
DPX-0907	Immunovaccine <i>Halifax, Canada</i>	breast cancer, ovarian cancer	Phase I (902) 492-1819
EC-145	Endocyte <i>West Lafayette, IN</i>	endometrial cancer, ovarian cancer	Phase II (765) 463-7175
EGEN 001 <b>(Orphan Drug)</b>	EGEN <i>Huntsville, AL</i>	recurrent ovarian cancer, recurrent fallopian tube cancer	Phase II (256) 512-0077
		refractory metastatic ovarian cancer	Phase I (256) 512-0077
ENMD-2076	EntreMed <i>Rockville, MD</i>	platinum-resistant ovarian cancer	Phase II (240) 864-2600
<b>Erbitux®</b> cetuximab	Bristol-Myers Squibb <i>Princeton, NJ</i> Eli Lilly <i>Indianapolis, IN</i> ImClone Systems <i>New York, NY</i>	breast cancer	Phase II (212) 546-4000 (800) 545-5979 (212) 645-1405
EVO 022	Evolve Oncology <i>New York, NY</i>	breast cancer	in clinical trials (646) 723-8941
EVO 033	Evolve Oncology <i>New York, NY</i>	breast cancer	in clinical trials (646) 723-8941
<b>Exelbine™</b> vinorelbine emulsion	ADVENTRX Pharmaceuticals <i>San Diego, CA</i>	breast cancer	application submitted (858) 552-0866
EZN-2208	Enzon Pharmaceuticals <i>Bridgewater, NJ</i>	metastatic breast cancer	Phase II (908) 541-8600
farletuzumab (MORAb-003)	Eisai <i>Woodcliff Lake, NJ</i>	ovarian cancer	Phase III (888) 422-4743
<b>Femara®</b> letrozole	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	endometrial cancer	Phase II (888) 669-6682
<b>Folotyn®</b> pralatrexate	Allos Therapeutics <i>Westminster, CO</i>	breast cancer	Phase II (303) 426-6262
FP-1039	Five Prime Therapeutics <i>San Francisco, CA</i>	endometrial cancer	Phase II (415) 365-5600
ganetespib	Synta Pharmaceuticals <i>Lexington, MA</i>	breast cancer	Phase II (781) 274-8200

# CANCER

Product Name	Company	Indication	Development Status
GDC-0941 (PI3 kinase inhibitor)	Genentech <i>South San Francisco, CA</i>	metastatic breast cancer	Phase I (650) 224-1000
GDC-0980 (PI3 kinase/mTOR dual inhibitor)	Genentech <i>South San Francisco, CA</i>	late-stage breast cancer	Phase I (650) 224-1000
GRN-163L (imetelstat)	Geron <i>Menlo Park, CA</i>	breast cancer	Phase II (650) 473-7700
<b>GVAX® Breast</b>	BioSante Pharmaceuticals <i>Lincolnshire, IL</i>	breast cancer	Phase I (847) 478-0500
<b>Halaven®</b> eribulin	Eisai <i>Woodcliff Lake, NJ</i>	second-line breast cancer	Phase III (888) 422-4743
<b>Herceptin® SC</b> rHuPH20/ trastuzumab	Halozyne <i>San Diego, CA</i> Roche <i>Nutley, NJ</i>	HER2-positive breast cancer	Phase III (858) 794-8889 (973) 235-5000
iboctadekin	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	ovarian cancer	Phase I (888) 825-5249
IMT-1012 (immunotherapeutic vaccine)	Immunotope <i>Doylestown, PA</i>	breast cancer, ovarian cancer	Phase I (215) 253-4180
iniparib (BSI-201)	BiPar Sciences <i>South San Francisco, CA</i> sanofi-aventis <i>Bridgewater, NJ</i>	metastatic triple negative breast cancer	Phase III (800) 633-1810
		neoadjuvant breast cancer, ovarian cancer	Phase II (800) 633-1810
interferon alpha-2b topical	Helix BioPharma <i>Aurora, Canada</i>	cervical dysplasia	Phase II completed (905) 841-2300
<b>Ixempra®</b> ixabepilone	Bristol-Myers Squibb <i>Princeton, NJ</i>	early-stage breast cancer	Phase II/III (212) 546-4000
		endometrial cancer	Phase II (212) 546-4000
<b>Karenitecin®</b> cositecan	BioNumerik Pharmaceuticals <i>San Antonio, TX</i>	advanced epithelial ovarian cancer	Phase III (210) 614-1701
KHK-2866	Kyowa Hakko Kirin Pharma <i>Princeton, NJ</i>	ovarian cancer	Phase I (609) 919-1100
KW-2450	Kyowa Hakko Kirin Pharma <i>Princeton, NJ</i>	breast cancer	Phase I/II (609) 919-1100
lenvatinib (E7080)	Eisai <i>Woodcliff Lake, NJ</i>	endometrial cancer	Phase II (888) 422-4743
LEP-ETU	NeoPharm <i>Lake Bluff, IL</i>	breast cancer	Phase II (847) 887-0800
LOR-2040	Lorus Therapeutics <i>Toronto, Canada</i>	metastatic breast cancer	Phase II (416) 798-1200

# CANCER

Product Name	Company	Indication	Development Status
<b>Lymphoseek™</b>	Neoprobe <i>Dublin, OH</i>	diagnosis of breast cancer	Phase III (800) 793-0079
<b>Mirena®</b> levonorgestrel-releasing intrauterine system	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	endometrial cancer	Phase II (888) 842-2937
MK-0752	Merck <i>Whitehouse Station, NJ</i>	breast cancer	Phase I (800) 672-6372
MK-2206	Merck <i>Whitehouse Station, NJ</i>	breast cancer	Phase I (800) 672-6372
MM-111	Merrimack Pharmaceuticals <i>Cambridge, MA</i>	breast cancer	Phase I/II (617) 441-1000
motesanib (AMG 708)	Amgen <i>Thousand Oaks, CA</i> Millennium Pharmaceuticals <i>Cambridge, MA</i>	breast cancer	Phase II (800) 772-6436 (800) 390-5663
<b>Myocet™</b> doxorubicin liposomal	Spherion Therapeutics <i>Princeton, NJ</i>	breast cancer (Fast Track)	Phase III (609) 986-2021
neratinib (HKI272)	Pfizer <i>New York, NY</i>	early-stage breast cancer, late-stage breast cancer	Phase III (860) 732-5156
<b>NeuVax™</b> E75 cancer vaccine	Apthera <i>Scottsdale, AZ</i>	breast cancer	Phase II <a href="http://www.apthera.com">www.apthera.com</a>
<b>Nexavar®</b> sorafenib	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> Onyx Pharmaceuticals <i>Emeryville, CA</i>	breast cancer, ovarian cancer	Phase II (888) 842-2937 (510) 597-6500
nimotuzumab	YM Biosciences USA <i>Lehigh Valley, PA</i>	breast cancer	Phase I completed (610) 560-0600
NK-012	Nippon Kayaku <i>Tokyo, Japan</i>	breast cancer	Phase II
NKTR-102	Nektar Therapeutics <i>San Francisco, CA</i>	breast cancer, ovarian cancer	Phase II (415) 482-5300
NOV-002	Novelos Therapeutics <i>Newton, MA</i>	early-stage breast cancer, ovarian cancer	Phase II (617) 244-1616
OBP-301	Oncolys Biopharma <i>Tokyo, Japan</i>	breast cancer	Phase I <a href="http://www.oncolys.com">www.oncolys.com</a>
OGX-427	Oncogenex Pharmaceuticals <i>Bothell, WA</i>	breast cancer, ovarian cancer	Phase I (425) 686-1500
olaparib	AstraZeneca <i>Wilmington, DE</i>	serous ovarian cancer	Phase II (800) 236-9933
ON-01910	Onconova Therapeutics <i>Princeton, NJ</i>	ovarian cancer	Phase II (609) 844-7735

# CANCER

Product Name	Company	Indication	Development Status
<b>Opaxio™</b> paclitaxel poliglumex	Cell Therapeutics <i>Seattle, WA</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	ovarian cancer	Phase III (800) 215-2355 (888) 669-6682
OPT-822/OPT-821	Optimer Pharmaceuticals <i>San Diego, CA</i>	breast cancer	Phase I (858) 909-0736
oregovomab	Quest Pharmatech <i>Edmonton, Canada</i>	ovarian cancer	Phase I/II (780) 448-1400
OSI-906 (linsitinib)	OSI Pharmaceuticals <i>Melville, NY</i>	ovarian cancer	Phase II (631) 962-2000
<b>OVax®</b> ovarian cancer vaccine <b>(Orphan Drug)</b>	AVAX Technologies <i>Philadelphia, PA</i>	ovarian cancer	Phase I/II (215) 241-9760
PD-0332991	Pfizer <i>New York, NY</i>	breast cancer	Phase I/II (860) 732-5156
perifosine (KRX-0401)	AEterna Zentaris <i>Montreal, Canada</i> Keryx Biopharmaceuticals <i>New York, NY</i>	ovarian cancer	Phase I (212) 531-5965
pertuzumab (RG 1273)	Roche <i>Nutley, NJ</i>	first-line metastatic HER2-positive breast cancer	Phase III (973) 235-5000
		early HER2-positive breast cancer, metastatic breast cancer	Phase II (973) 235-5000
PF-01367338	Pfizer <i>New York, NY</i>	breast cancer, ovarian cancer	Phase II (860) 732-5156
phenoxodiol	Marshall Edwards <i>San Diego, CA</i>	late-stage ovarian cancer (Fast Track)	Phase III (858) 792-6300
		fallopian tube cancer	Phase I/II (858) 792-6300
picoplatin intravenous	Poniard Pharmaceuticals <i>San Francisco, CA</i>	ovarian cancer	Phase II (650) 583-3774
<b>Pixuvri™</b> pixantrone	Cell Therapeutics <i>Seattle, WA</i>	metastatic breast cancer	Phase II (800) 215-2355
PM-00104	PharmaMar USA <i>Cambridge, MA</i>	cervical cancer, endometrial cancer	Phase II (617) 868-3797
PTC299	PTC Therapeutics <i>South Plainfield, NJ</i>	breast cancer	Phase I/II (908) 222-7000
PV701	Wellstat Biologics <i>Gaithersburg, MD</i>	cervical cancer	Phase II (240) 631-2500
PX-1032 (HER2 breast cancer vaccine)	BN ImmunoTherapeutics <i>Mountain View, CA</i>	breast cancer	Phase I (650) 681-4660

# CANCER

Product Name	Company	Indication	Development Status
<b>Quinamed®</b> amonafide	ChemGenex Pharmaceuticals <i>Menlo Park, CA</i>	breast cancer, ovarian cancer	Phase II (650) 474-9800
ramucirumab (IMC-1121B)	Eli Lilly <i>Indianapolis, IN</i> ImClone Systems <i>New York, NY</i>	breast cancer	Phase III (800) 545-5979 (212) 645-1405
<b>Reximmune-C™</b> personalized cancer vaccine	Epeius Biotechnologies <i>San Marino, CA</i>	breast cancer	Phase I/II (626) 441-6695
<b>Rexin-G™</b> tumor-targeted gene therapy	Epeius Biotechnologies <i>San Marino, CA</i>	recurrent, refractory metastatic breast cancer	Phase I/II (626) 441-6695
ridaforolimus	Merck <i>Whitehouse Station, NJ</i>	breast cancer	Phase II (800) 672-6372
sagopilone	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	breast cancer, ovarian cancer	Phase II (888) 842-2937
SAR245408 (XL-147) (oral P13K inhibitor)	Exelixis <i>South San Francisco, CA</i> sanofi-aventis <i>Bridgewater, NJ</i>	endometrial cancer	Phase II (650) 837-7000 (800) 633-1810
SAR256212 (MM-121)	Merrimack Pharmaceuticals <i>Cambridge, MA</i> sanofi-aventis <i>Bridgewater, NJ</i>	breast cancer  ----- ovarian cancer	Phase II (617) 441-1000 (800) 633-1810  Phase I (617) 441-1000 (800) 633-1810
SF1 (sonodynamic therapy)	SonneMed <i>Boston, MA</i>	advanced breast cancer	Phase I/II <a href="http://www.sonnemed.com">www.sonnemed.com</a>
SG2000	Spirogen <i>London, United Kingdom</i>	ovarian cancer	Phase II <a href="http://www.spirogen.com">www.spirogen.com</a>
SDX-275 (entinostat)	Syndax Pharmaceuticals <i>Waltham, MA</i>	breast cancer	Phase II (781) 419-1400
<b>Sprycel®</b> dasatinib	Bristol-Myers Squibb <i>Princeton, NJ</i>	breast cancer (see also autoimmune)	Phase II (212) 546-4000
squalamine	OHR Pharmaceuticals <i>New York, NY</i>	resistant ovarian cancer (see also eye)	Phase II completed (212) 682-8452
<b>Tarceva®</b> erlotinib	Genentech <i>South San Francisco, CA</i> OSI Pharmaceuticals <i>Melville, NY</i>	breast cancer	Phase II (650) 224-1000 (800) 572-1932
TAS-108	Taiho Pharma USA <i>Princeton, NJ</i>	breast cancer	Phase II (609) 750-5300



# CANCER

Product Name	Company	Indication	Development Status
<b>Telcyta®</b> canfosfamide	Telik <i>Palo Alto, CA</i>	ovarian cancer	Phase III completed (650) 845-7700
terameprocol (intravaginal)	Erimos Pharmaceuticals <i>Houston, TX</i>	cervical intraepithelial neoplasia	Phase II (713) 541-2000
tesetaxel	Genta <i>Berkeley Heights, NJ</i>	advanced breast cancer	Phase II (908) 286-9800
TG4001 (RG3484)	Roche <i>Nutley, NJ</i> Transgene <i>Kensington, MD</i>	cervical intraepithelial neoplasia	Phase II (973) 235-5000 (301) 816-5404
<b>ThermoDox®</b> LTSDEL	Celsion <i>Columbia, MD</i>	recurrent breast cancer	Phase I/II (410) 290-5390
tigatuzumab	Daiichi Sankyo <i>Parsippany, NJ</i>	ovarian cancer	Phase II (973) 359-2600
topotecan liposomal	Talon Therapeutics <i>South San Francisco, CA</i>	ovarian cancer	Phase I (650) 588-6404
trabectedin	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	ovarian cancer	application submitted (800) 817-5286
		metastatic breast cancer	Phase III (800) 817-5286
trastuzumab emtansine	Genentech <i>South San Francisco, CA</i> ImmunoGen <i>Waltham, MA</i>	advanced metastatic HER2-positive breast cancer, metastatic HER2- positive breast cancer	Phase III (800) 626-3553 (781) 895-0600
		early HER2-positive breast cancer	Phase II (800) 626-3553 (781) 895-0600
<b>Tykerb®</b> lapatinib	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	breast cancer (adjuvant therapy)	Phase III (888) 825-5249
V503	Merck <i>Whitehouse Station, NJ</i>	cervical cancer prevention, vulvovaginal cancer prevention (see also obstetric/gynecologic)	Phase III (800) 672-6372
V505	Merck <i>Whitehouse Station, NJ</i>	cervical cancer prevention (see also obstetric/gynecologic)	Phase II (800) 672-6372
VGX-3100	Inovio Pharmaceuticals <i>Blue Bell, PA</i>	cervical intraepithelial neoplasia (see also obstetric/gynecologic)	Phase II (267) 440-4200
volasertib	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	ovarian cancer	Phase II (800) 243-0127
volociximab	Biogen Idec <i>Cambridge, MA</i> Facet Biotech <i>Redwood City, CA</i>	ovarian cancer (see also eye)	Phase II (617) 679-2000 (650) 454-1000
vosaroxin (SNS-595)	Sunesis Pharmaceuticals <i>South San Francisco, CA</i>	platinum-resistant ovarian cancer	Phase II (650) 266-3500

## CANCER

Product Name	Company	Indication	Development Status
<b>Votrient®</b> pazopanib	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	ovarian cancer (see also eye)	Phase III (888) 825-5249
<b>Votrient®</b> pazopanib and <b>Tykerb®</b> lapatinib	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	inflammatory breast cancer	Phase III (888) 825-5249
WX-671	Wilex <i>Munich, Germany</i>	metastatic breast cancer	Phase II www.wilex.com
YM-155	Astellas Pharma US <i>Deerfield, IL</i>	breast cancer	Phase II (800) 727-7003
ZIO-301 (indibulin)	ZIOPHARM Oncology <i>New York, NY</i>	late-stage breast cancer	Phase I/II (646) 214-0700
<b>Zolinza®</b> vorinostat	Merck <i>Whitehouse Station, NJ</i>	breast cancer, gynecological cancer	Phase II (800) 672-6372
<b>Zybrexat™</b> fosbretabulin (Orphan Drug)	OXIGENE <i>South San Francisco, CA</i>	ovarian cancer	Phase II (650) 635-7000

## EYE DISORDERS

Product Name	Company	Indication	Development Status
AAV2sFLT 01	Applied Genetic Technologies <i>Alachua, FL</i> Genzyme <i>Cambridge, MA</i>	age-related macular degeneration (wet form)	Phase I (386) 462-2204 (617) 252-7500
AC-262271	ACADIA Pharmaceuticals <i>San Diego, CA</i> Allergan <i>Irvine, CA</i>	glaucoma	Phase I (858) 558-2871 (800) 347-4500
ACU-4429	Acucela <i>Seattle, WA</i>	age-related macular degeneration (dry form)	Phase II (206) 805-8300
aflibercept	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> Regeneron Pharmaceuticals <i>Tarrytown, NY</i>	age-related macular degeneration	application submitted (888) 842-2937 (914) 345-7400
AL-38583	Alcon <i>Fort Worth, TX</i>	dry eyes	Phase II (800) 862-5266
AL-39324	Alcon <i>Fort Worth, TX</i>	age-related macular degeneration	Phase II (800) 862-5266
AL-43546	Alcon <i>Fort Worth, TX</i>	dry eyes	Phase II (800) 862-5266
ALTY-0501	Alacrity Biosciences <i>Laguna Hills, CA</i>	dry eyes	Phase II (949) 951-1348

## EYE DISORDERS

Product Name	Company	Indication	Development Status
ALTY-0601	Alacrity Biosciences <i>Laguna Hills, CA</i>	glaucoma	Phase I (949) 951-1348
AR-12286	Aerie Pharmaceuticals <i>Bridgewater, NJ</i>	glaucoma	Phase II (908) 685-0069
ARC1905	Ophthotech <i>Princeton, NJ</i>	age-related macular degeneration (dry and wet forms)	Phase I (609) 945-6050
AT-003 (mecamylamine ophthalmic)	CoMentis <i>South San Francisco, CA</i>	age-related macular degeneration	Phase II
BOL-303242-X	Bausch & Lomb <i>Madison, NJ</i>	dry eyes	Phase II (877) 442-6925
BOL-303259-X	Bausch & Lomb <i>Madison, NJ</i>	glaucoma	Phase II (877) 442-6925
brimonidine/ brinzolamide combination	Alcon <i>Fort Worth, TX</i>	glaucoma	Phase II (800) 862-5266
CF101	CanFite BioPharma <i>Petah-Tikva, Israel</i>	dry eyes (see also arthritis/musculoskeletal)	Phase III www.can-fite.com
ciclosporin A ophthalmic	Alcon <i>Fort Worth, TX</i>	dry eyes	Phase III completed (800) 862-5266
CNTO 2476	Centocor Ortho Biotech <i>Horsham, PA</i>	age-related macular degeneration	Phase I/II (800) 457-6399
DE-104	Santen <i>Napa, CA</i>	glaucoma	Phase II (707) 254-1750
DNB-001	Danube Pharmaceuticals <i>New York, NY</i>	glaucoma	Phase II (646) 375-4641
<b>DuoTrav™ APS</b> travoprost/timolol	Alcon <i>Fort Worth, TX</i>	glaucoma	Phase III (800) 862-5266
<b>Durezol™</b> difluprednate ophthalmic	Alcon <i>Fort Worth, TX</i>	dry eyes	Phase II (800) 862-5266
E10030	Ophthotech <i>Princeton, NJ</i>	age-related macular degeneration (wet form)	Phase I (609) 945-6050
ecabet ophthalmic	ISTA Pharmaceuticals <i>Irvine, CA</i>	dry eyes	Phase II (949) 788-6000
EGP-437	EyeGate Pharma <i>Waltham, MA</i>	dry eyes	Phase III (781) 788-8869
fenretinide (RT-101)	ReVision Therapeutics <i>San Diego, CA</i>	age-related macular degeneration	Phase II (858) 768-7860
fluocinolone acetone ophthalmic	Alimera Sciences <i>Alpharetta, GA</i>	age-related macular degeneration	Phase II (678) 990-5740
hyaluronic ophthalmic	Lantbio <i>Chapel Hill, NC</i>	dry eyes	application submitted (919) 960-0217

## EYE DISORDERS

Product Name	Company	Indication	Development Status
INO-8875	Inotek Pharmaceuticals <i>Lexington, MA</i>	glaucoma	Phase II (781) 676-2100
INS115644	Inspire Pharmaceuticals <i>Durham, NC</i>	glaucoma	Phase I completed (919) 941-9777
INS117548	Inspire Pharmaceuticals <i>Durham, NC</i>	glaucoma	Phase I completed (919) 941-9777
IOP lowering (EP agonist)	Allergan <i>Irvine, CA</i>	glaucoma	Phase II (714) 246-4500
IOP lowering (sustained-release)	Allergan <i>Irvine, CA</i>	glaucoma	Phase II (714) 246-4500
<b>ISONEP™</b> sonepcizumab	Lpath <i>San Diego, CA</i>	age-related macular degeneration	Phase I (858) 678-0800
LD22-4	Advanced Refractive Technologies <i>San Clemente, CA</i>	age-related macular degeneration	Phase I (949) 940-1300
<b>Lucentis®</b> ranibizumab (neovascular)	Genentech <i>South San Francisco, CA</i>	age-related macular degeneration	Phase III (800) 626-3553
LX214 topical	Lux Biosciences <i>Jersey City, NJ</i>	dry eyes	Phase I (201) 946-0551
MC-1101	MacuCLEAR <i>Plano, TX</i>	age-related macular degeneration (dry form or early-stage)	Phase I <a href="http://www.macuclear.com">www.macuclear.com</a>
MIM-D3	Mimetogen Pharmaceuticals <i>Montreal, Canada</i>	dry eyes	Phase II <a href="http://www.mimetogen.com">www.mimetogen.com</a>
mitomycin ophthalmic	Mobius Therapeutics <i>St. Louis, MO</i>	glaucoma	application submitted (314) 615-6930
Nova12027 (latanoprost emulsion)	Novagali Pharma <i>Evry Cedex, France</i>	glaucoma	Phase II <a href="http://www.novagali.com">www.novagali.com</a>
Nova22007 (ciclosporin ophthalmic)	Novagali Pharma <i>Evry Cedex, France</i>	dry eyes	Phase II completed <a href="http://www.novagali.com">www.novagali.com</a>
NT-501	Neurotech <i>Lincoln, RI</i>	age-related macular degeneration (dry form)	Phase II (401) 333-3880
ocriplasmin	ThromboGenics <i>New York, NY</i>	age-related macular degeneration (wet form)	Phase II (212) 201-0920
<b>Ozurdex™</b> dexamethasone ophthalmic	Allergan <i>Irvine, CA</i>	age-related macular degeneration	Phase II (714) 246-4500
P-529	Paloma Pharmaceuticals <i>Jamaica Plain, MA</i>	age-related macular degeneration	Phase I (617) 522-7681
PF-04217329 (taprenepag isopropyl)	Pfizer <i>New York, NY</i>	glaucoma	Phase II (860) 732-5156
PF-04382923	Pfizer <i>New York, NY</i>	age-related macular degeneration	Phase I (860) 732-5156

## EYE DISORDERS

Product Name	Company	Indication	Development Status
PF-04523655 (small interfering RNA)	Pfizer <i>New York, NY</i>	age-related macular degeneration	Phase II (860) 732-5156
pimecrolimus topical	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	dry eyes	in clinical trials (888) 669-6682
POT-4	Alcon <i>Fort Worth, TX</i>	age-related macular degeneration (wet and dry forms)	Phase I (800) 862-5266
rebamipide ophthalmic	Acucela <i>Bothell, WA</i> Otsuka America Pharmaceutical <i>Rockville, MD</i>	dry eyes	Phase II (425) 527-3260 (800) 562-3974
<b>Remura™</b> bromfenac (lower concentration)	ISTA Pharmaceuticals <i>Irvine, CA</i>	dry eyes	Phase III (949) 788-6000
<b>Restasis® X</b> cyclosporin ophthalmic emulsion	Allergan <i>Irvine, CA</i>	age-related macular degeneration	Phase II (714) 246-4500
<b>RetinoStat®</b> gene therapy	sanofi-aventis <i>Bridgewater, NJ</i>	age-related macular degeneration (wet form)	Phase I (800) 633-1610
RG7417 (anti-factor D)	Genentech <i>South San Francisco, CA</i>	age-related macular degeneration	Phase I (800) 626-3553
RGN-259 (thymosin beta-5)	RegeneRx Biopharmaceuticals <i>Rockville, MD</i>	dry eyes	Phase II (301) 208-9191
rivoglitazone ophthalmic	Santen <i>Napa, CA</i>	dry eyes	Phase II (707) 254-1750
RX-10045	Resolvix Pharmaceuticals <i>Bedford, MA</i>	dry eyes	Phase II completed (781) 541-5045
SAR 1118	SARcode <i>Brisbane, CA</i>	dry eyes	Phase II (650) 416-7560
sirolimus ophthalmic	Santen <i>Napa, CA</i>	dry eyes	Phase II (707) 254-1750
		age-related macular degeneration	Phase I/II (707) 254-1750
<b>Solaris®</b> eculizumab	Alexion Pharmaceuticals <i>Cheshire, CT</i>	age-related macular degeneration (see also autoimmune)	Phase II (203) 272-2596
squalamine	Ohr Pharmaceutical <i>New York, NY</i>	age-related macular degeneration (wet form) (see also cancer)	Phase II completed (212) 682-8452
stem cell therapy	Stemedica Cell Technologies <i>San Diego, CA</i>	glaucoma, macular degeneration	in clinical trials (858) 658-0910

## EYE DISORDERS

Product Name	Company	Indication	Development Status
tafluprost ophthalmic	Merck <i>Whitehouse Station, NJ</i> Santen <i>Napa, CA</i>	glaucoma	Phase III (888) 669-6682 (707) 254-1750
tofacinib ophthalmic	Pfizer <i>New York, NY</i>	dry eyes	Phase II (860) 732-5156
volociximab	Ophthotech <i>Princeton, NJ</i>	age-related macular degeneration (wet form) (see also cancer)	Phase I (609) 945-6050
<b>Votrient®</b> pazopanib	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	age-related macular degeneration (eye drops) (see also cancer)	Phase II (888) 825-5249
		age-related macular degeneration (oral)	Phase I (888) 825-5249

## GASTROINTESTINAL DISORDERS

Product Name	Company	Indication	Development Status
AGN-XX/YY	ACADIA Pharmaceuticals <i>San Diego, CA</i> Allergan <i>Irvine, CA</i>	irritable bowel syndrome associated pain (see also arthritis/musculoskeletal)	Phase II (858) 558-2871 (800) 433-8871
asimadoline	Tioga Pharmaceuticals <i>San Diego, CA</i>	irritable bowel syndrome	Phase III (858) 677-6077
AST120	Ocera Therapeutics <i>San Diego, CA</i>	non-constipating irritable bowel syndrome	Phase II (858) 436-3900
crofelemer	Salix Pharmaceuticals <i>Morrisville, NC</i>	diarrhea-predominant irritable bowel syndrome (Fast Track)	Phase II (919) 862-1000
dextofisopam	Pharmos <i>Inselin, NJ</i>	irritable bowel syndrome	Phase II (609) 771-8660
JNJ-27018966	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	diarrhea-predominant irritable bowel syndrome (Fast Track)	Phase II (800) 817-5286
larazotide	Alba Therapeutics <i>Baltimore, MD</i>	irritable bowel syndrome	Phase I (410) 319-0780
linaclotide	Forest Laboratories <i>New York, NY</i> Ironwood Pharmaceuticals <i>Cambridge, MA</i>	constipation-predominant irritable bowel syndrome	Phase III (800) 947-5227 (617) 621-7722
LX1031	Lexicon Pharmaceuticals <i>The Woodlands, TX</i>	irritable bowel syndrome	Phase II (281) 863-3000
SP-304 (plecanatide)	Synergy Pharmaceuticals <i>New York, NY</i>	constipation-predominant irritable bowel syndrome	Phase I completed (212) 297-0020

## GASTROINTESTINAL DISORDERS

Product Name	Company	Indication	Development Status
TC-6499	Targacept <i>Winston-Salem, NC</i>	constipation-predominant irritable bowel syndrome	Phase II completed (336) 480-2100
<b>Xifaxan®</b> rifaximin	Salix Pharmaceuticals <i>Morrisville, NC</i>	non-constipating irritable bowel syndrome	application submitted (919) 862-1000
YKP10811	SK Drug Development Center <i>Fairlawn, NJ</i>	irritable bowel syndrome	Phase I (201) 421-3864

## KIDNEY/UROLOGIC DISORDERS

Product Name	Company	Indication	Development Status
AA-4010 (oxybutynin transmucosal film)	Auxilium Pharmaceuticals <i>Malvern, PA</i>	overactive bladder	Phase I (484) 321-5900
ACHN-490	Achaogen <i>South San Francisco, CA</i>	urinary tract infections	Phase II (650) 266-1120
AGN-214868 (targeted toxin)	Allergan <i>Irvine, CA</i> Syntaxin <i>Oxon, United Kingdom</i>	overactive bladder with urinary incontinence	Phase II (714) 246-4500
anti-TWEAK (BIIB 023)	Biogen Idec <i>Cambridge, MA</i>	lupus nephritis (see also arthritis/musculoskeletal)	Phase I (617) 679-2000
<b>Anturol®</b> oxybutynin transdermal gel	Antares Pharma <i>Ewing, NJ</i>	overactive bladder	application submitted (609) 359-3020
AOBO-001	American Oriental Engineering <i>Jersey City, NJ</i>	overactive bladder	Phase II (646) 367-1718
ASP-3652	Astellas Pharma US <i>Deerfield, IL</i>	overactive bladder	Phase I (800) 477-6472
<b>Botok®</b> onabotulinum toxinA	Allergan <i>Irvine, CA</i>	neurogenic detrusor overactivity	application submitted (714) 246-4500
		idiopathic overactive bladder	Phase III (714) 246-4500
C-1205	ConjuGon <i>Madison, WI</i>	prevention of catheter-associated urinary tract infections	Phase I (608) 441-2794
ceftaroline/NXL104 (CXL104/CEF104)	AstraZeneca <i>Wilmington, DE</i> Forest Laboratories <i>New York, NY</i>	urinary tract infections	Phase II (800) 236-9933 (800) 947-5227
<b>CellCept®</b> mycophenolate mofetil	Aspreva Pharmaceuticals <i>Basking Ridge, NJ</i>	lupus nephritis (see also autoimmune)	Phase III (908) 212-1020
CNTO-136 (sirukumab)	Centocor Ortho Biotech <i>Horsham, PA</i>	lupus nephritis (see also arthritis/musculoskeletal)	Phase II (610) 651-6000



## KIDNEY/UROLOGIC DISORDERS

Product Name	Company	Indication	Development Status
CTV-05	Osel <i>Santa Clara, CA</i>	urinary tract infections (see also obstetric/gynecologic)	Phase II (408) 986-0012
CXA-101	Cubist Pharmaceuticals <i>Lexington, MA</i>	urinary tract infections	Phase II completed (781) 860-8660
CXA-201 (CXA-101/ tazobactam combo IV)	Cubist Pharmaceuticals <i>Lexington, MA</i>	complicated urinary tract infections (see also lung/respiratory)	Phase II (781) 860-8660
DR-3001 (oxybutynin vaginal)	Duramed Research <i>Bala Cynwyd, PA</i>	overactive bladder	Phase III completed (610) 747-2600
FP1097	FemmePharma Global Healthcare <i>Wayne, PA</i>	urinary incontinence	Phase II completed (610) 995-0801
hMaxi-K gene therapy	Ion Channel Innovations <i>New York, NY</i>	overactive bladder	Phase I (212) 639-1561
<b>Humira®</b> adalimumab	Abbott Laboratories <i>Abbott Park, IL</i>	interstitial cystitis (see also arthritis/musculoskeletal)	Phase III (847) 937-6100
<b>LiRIS®</b> lidocaine intravesicular	TARIS Biomedical <i>Lexington, MA</i>	interstitial cystitis	Phase I (781) 676-7750
MCP-202	Mount Cook Pharma <i>Princeton, NJ</i>	urinary incontinence	Phase I completed (609) 297-2100
mirabegron	Astellas Pharma US <i>Deerfield, IL</i>	overactive bladder	Phase III (800) 727-7003
MN-246	MediciNova <i>San Diego, CA</i>	urinary frequency, urinary incontinence	Phase I (858) 373-1500
<b>Myfortic®</b> mycophenolic acid delayed-release tablets	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	lupus nephritis	Phase II/III completed (888) 669-6682
NVC-422	NovaBay Pharmaceuticals <i>Emeryville, CA</i>	catheter-associated urinary tract infections	Phase II (510) 899-8800
NXL-104/ ceftazidime	AstraZeneca <i>Wilmington, DE</i> Forest Laboratories <i>New York, NY</i>	urinary tract infections	Phase II (800) 236-9933 (800) 947-5227
<b>Orencia®</b> abatacept	Bristol-Myers Squibb <i>Princeton, NJ</i>	lupus nephritis (see also arthritis/musculoskeletal, autoimmune)	Phase I (212) 546-4000
PSD-597	Plethora Solutions <i>London, England</i>	interstitial cystitis	Phase II
resiniferatoxin (MCP-101)	Mount Cook Pharma <i>Princeton, NJ</i>	overactive bladder	Phase II (609) 297-2100
SMP-986	Sunovion Pharmaceuticals <i>Marlborough, MA</i>	overactive bladder	Phase II (508) 481-6700

## KIDNEY/UROLOGIC DISORDERS

Product Name	Company	Indication	Development Status
SVT-40776 (tarafenacin)	SALVAT USA <i>Coral Gables, FL</i>	overactive bladder	Phase II (305) 774-9727
tipelukast	MediciNova <i>San Diego, CA</i>	interstitial cystitis	Phase II/III completed (858) 373-1500
URG101	Urigen Pharmaceuticals <i>San Francisco, CA</i>	interstitial cystitis	Phase II (415) 781-0350
URG301	Urigen Pharmaceuticals <i>San Francisco, CA</i>	overactive bladder	Phase I (415) 781-0350
UTI vaccine	Xanodyne Pharmaceuticals <i>Florence, KY</i>	urinary tract infections	Phase II (859) 371-6383

## LUNG/RESPIRATORY DISORDERS

Product Name	Company	Indication	Development Status
ABT-308	Abbott Laboratories <i>Abbott Park, IL</i>	asthma	Phase I (847) 937-6100
aclidinium	Forest Laboratories <i>New York, NY</i>	chronic obstructive pulmonary disease (COPD)	Phase III (800) 947-5227
aclidinium/ formoterol	Forest Laboratories <i>New York, NY</i>	COPD	Phase II (800) 947-5227
ACT-129968	Actelion Pharmaceuticals US <i>South San Francisco, CA</i>	asthma	Phase II (650) 624-6900
ADS-8902	Adamas Pharmaceuticals <i>Emeryville, CA</i>	influenza A virus H1N1 subtype, influenza A virus infections	Phase II (510) 450-3500
<b>Aerovant™</b> pitrakinra	Aerovance <i>Berkeley, CA</i>	asthma	Phase II (510) 549-5500
AM211/461	Amira Therapeutics <i>San Diego, CA</i>	asthma, COPD	Phase I (858) 228-4650
AMG 157 (mAb)	Amgen <i>Thousand Oaks, CA</i>	asthma	Phase I (800) 772-6436
AMG 761 (CCR4 receptor antagonist)	Amgen <i>Thousand Oaks, CA</i>	asthma	Phase I (800) 772-6436
AMG 827 (mAb)	Amgen <i>Thousand Oaks, CA</i>	asthma (see also arthritis/musculoskeletal)	Phase II (800) 772-6436
AMG 853 (prostaglandin D2 receptor antagonist)	Amgen <i>Thousand Oaks, CA</i>	asthma	Phase I (800) 772-6436
anti-M1 prime mAb (RG7449)	Genentech <i>South San Francisco, CA</i>	asthma	Phase II (800) 626-3553
ASM8	Topigen Pharmaceuticals <i>Montreal, Canada</i>	asthma	Phase II completed (514) 868-0077

## LUNG/RESPIRATORY DISORDERS

Product Name	Company	Indication	Development Status
ATL844	PGxHealth New Haven, CT	asthma	Phase II (877) 274-9432
AVX-502	AlphaVax Rsch. Triangle Park, NC	influenza virus infections	Phase I/II (919) 595-0400
AZD1981 (CRTh2 receptor antagonist)	AstraZeneca Wilmington, DE	asthma, COPD	Phase II (800) 236-9933
AZD2115	AstraZeneca Wilmington, DE	COPD	Phase I (800) 236-9933
AZD2423 (CCR2b antagonist)	AstraZeneca Wilmington, DE	COPD	Phase II (800) 236-9933
AZD3199 (iLABA)	AstraZeneca Wilmington, DE	asthma, COPD	Phase II (800) 236-9933
AZD5069 (CXCR2)	AstraZeneca Wilmington, DE	COPD	Phase II (800) 236-9933
AZD5423 (inhaled SEGRA)	AstraZeneca Wilmington, DE	COPD	Phase II (800) 236-9933
AZD8683 (muscarinic antagonist)	AstraZeneca Wilmington, DE	COPD	Phase II (800) 236-9933
AZD8848 (toll-like receptor 7 agonist)	AstraZeneca Wilmington, DE	asthma	Phase II (800) 236-9933
AZD9819 (neutrophil elastase inhibitor)	AstraZeneca Wilmington, DE	COPD	Phase I (800) 236-9933
BAY 41-6551 (amikacin inhalation)	Bayer HealthCare Pharmaceuticals Wayne, NJ Nektar Therapeutics San Francisco, CA	nosocomial pneumonia	Phase II (888) 842-2937 (415) 482-5300
bedoradrine (MN-221)	MediciNova San Diego, CA	asthma, status asthmaticus (see also obstetric/gynecologic)	Phase II (858) 373-1500
		COPD	Phase I (858) 373-1500
BI 1744 (olodaterol)	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	COPD	Phase III (800) 243-0127
		asthma	Phase II (800) 243-0127
BI 1744CL (olodaterol/ tiotropium bromide fixed-dose combination)	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	COPD	Phase II (800) 243-0127

## LUNG/RESPIRATORY DISORDERS

Product Name	Company	Indication	Development Status
BI 671800	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	asthma	Phase II (800) 243-0127
BIO-11006	BioMarck Pharmaceuticals <i>Raleigh, NC</i>	COPD	Phase II
BTL-TML001	Beech Tree Labs <i>Providence, RI</i>	influenza virus infections	Phase I/II (401) 273-2060
CAT-354 (tralokinumab) anti-IL-13 mAb	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	asthma	Phase II (800) 236-9933 (301) 398-0000
cell culture-derived influenza vaccine	Abbott Laboratories <i>Abbott Park, IL</i>	prevention of influenza virus infections	Phase I (847) 937-6100
CNTO 3157	Centocor Ortho Biotech <i>Horsham, PA</i>	asthma	Phase I (800) 457-6399
CNTO 5825	Centocor Ortho Biotech <i>Horsham, PA</i>	allergic asthma	Phase I (800) 457-6399
CXA-201 (CXA-101/ tazobactam combo IV)	Cubist Pharmaceuticals <i>Lexington, MA</i>	nosocomial pneumonia (see also kidney/urologic)	Phase I (886) 792-2786
DAS181	NexBio <i>San Diego, CA</i>	influenza A virus H1N1 subtype, influenza virus infections	Phase II (858) 452-2631
		prevention of influenza virus infections	Phase I (858) 452-2631
<b>Doribax®</b> doripenem	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	nosocomial pneumonia	application submitted (800) 817-5285
<b>Dulera®</b> mometasone furoate/formoterol fumarate dihydrate inhalation aerosol	Merck <i>Whitehouse Station, NJ</i>	COPD	Phase III completed (800) 672-6372
EDP-420	Enanta Pharmaceuticals <i>Watertown, MA</i>	community-acquired pneumonia	Phase II (617) 607-0800
EP-101	Elevation Pharmaceuticals <i>San Diego, CA</i>	severe asthma	Phase III (858) 436-1616
		COPD	Phase I (858) 436-1616
EPI-12323	EpiGenesis Pharmaceuticals <i>Cranbury, NJ</i>	asthma, COPD	Phase II (609) 409-6080
<b>Excellair™</b> syk kinase silencer	ZaBeCor Pharmaceuticals <i>Bala Cynwyd, PA</i>	asthma	Phase II (610) 660-7733

## LUNG/RESPIRATORY DISORDERS

Product Name	Company	Indication	Development Status
favipiravir	Toyama USA <i>Valhalla, NY</i>	influenza virus infections	Phase II (914) 220-4600
<b>FluBlok®</b> influenza virus vaccine	Protein Sciences <i>Meriden, CT</i>	prevention of influenza virus infections	application submitted (800) 488-7099
<b>FluNhance™</b> recombinant neuraminidase	Protein Sciences <i>Meriden, CT</i>	influenza virus infections	Phase II completed (800) 488-7099
<b>Flutiform™</b> formoterol/ fluticasone propionate	SkyePharma <i>San Diego, CA</i>	asthma	application submitted (858) 625-2424
<b>Fluzone® ID</b> seasonal influenza vaccine intradermal micro-injection	sanofi pasteur <i>Swiftwater, PA</i>	influenza virus infections	application submitted (800) 822-2463
<b>Fluzone® QIV</b> quadrivalent inactivated influenza vaccine	sanofi pasteur <i>Swiftwater, PA</i>	influenza virus infections	Phase III (800) 822-2463
formoterol/ fluticasone propionate	Dey Pharma <i>Basking Ridge, NJ</i>	COPD	Phase II (908) 542-1999
GSK256066 (PDE4 inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma, COPD	Phase II (888) 825-5249
GSK573719 (muscarinic receptor antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase III (888) 825-5249
GSK573719/ vilanterol combination	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase III (888) 825-5249
GSK610677 (p38 kinase inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase I completed (888) 825-5249
GSK679586 (mAb)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma	Phase I completed (888) 825-5249
GSK685698 (glucocorticoid agonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma	Phase II (888) 825-5249
GSK766994 (CCR3 antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma	Phase II (888) 825-5249
GSK870086 (novel glucocorticoid receptor agonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma	Phase II (888) 825-5249

## LUNG/RESPIRATORY DISORDERS

Product Name	Company	Indication	Development Status
GSK961081 (beta 2 agonist and muscarinic antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase II (888) 825-5249
GSK1325756 (CXCR2 receptor antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase I (888) 825-5249
GSK1440115 (urotensin antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma	Phase I (888) 825-5249
GSK2186877A (influenza virus vaccine)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	influenza virus infections	Phase III (888) 825-5249
GSK2190914 (5-FLAP inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma	Phase II (888) 825-5249
GSK2190915 (5-FLAP inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma	Phase II (888) 825-5249
GSK2245840 (SIRT1 activator)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase I (888) 825-5249
GSK2282512A (quadrivalent seasonal flu vaccine)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of influenza virus infections	Phase III (888) 825-5249
GSK2321138A (influenza virus vaccine)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	influenza virus infections	Phase III (888) 825-5249
H5N1 influenza virus vaccine	Novavax <i>Rockville, MD</i>	prevention of influenza A virus H5N1 subtype	Phase II (240) 268-2000
H5N1 influenza virus vaccine intranasal	Nanotherapeutics <i>Alachua, FL</i>	influenza virus infections	Phase I (386) 462-9663
H5N1 (pre-)pandemic influenza virus vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of influenza A virus H5N1 subtype	Phase III (888) 825-5249
<b>Ilaris®</b> canakinumab	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	COPD (see also arthritis/musculoskeletal, autoimmune)	Phase II completed (888) 669-6682
IMO-2134	Idera Pharmaceuticals <i>Cambridge, MA</i>	asthma	Phase I (617) 679-5500
indacaterol (QAB149)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	COPD	application submitted (888) 669-6682
		asthma	Phase III completed (888) 669-6682

## LUNG/RESPIRATORY DISORDERS

Product Name	Company	Indication	Development Status
indacaterol/ mometasone (QMF149)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	asthma, COPD	Phase II (888) 669-6682
influenza A virus H1N1 vaccine	Baxter International <i>Deerfield, IL</i>	prevention of influenza A virus H1N1 subtype	Phase I/II (800) 422-9837
influenza A virus H1N1 vaccine	CEL-SCI <i>Vienna, VA</i>	prevention and treatment of influenza A virus H1N1 subtype	in clinical trials (703) 506-9460
influenza A virus H1N1 vaccine	iBio <i>Newark, DE</i>	prevention of influenza A virus H1N1 subtype	Phase I (302) 355-9452
influenza A virus H5N1 cell culture based vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of influenza A virus H5N1 subtype (pandemic use)	Phase I (888) 825-5249
influenza A virus H5N1 vaccine	Baxter International <i>Deerfield, IL</i>	prevention of influenza A virus H5N1 subtype	Phase I/II (800) 422-9837
influenza A virus H5N1 vaccine	iBio <i>Newark, DE</i>	influenza A virus H5N1 subtype	Phase I (302) 355-9452
influenza A virus H5N1 vaccine	Novartis Vaccines <i>Cambridge, MA</i>	prevention of influenza A virus H5N1 subtype	Phase II (888) 669-6682
influenza A virus H9N2 vaccine	Baxter International <i>Deerfield, IL</i>	prevention of influenza A virus H9N2 subtype	Phase I/II (800) 422-9837
influenza virus DNA vaccine (H1N1 subtype)	Vical <i>San Diego, CA</i>	prevention of influenza A virus H1N1 subtype	Phase I (858) 646-1100
influenza virus DNA vaccine (H5N1 subtype)	Vical <i>San Diego, CA</i>	prevention of influenza virus A H5N1 subtype	Phase I (858) 646-1100
influenza virus-like particle vaccine	Novavax <i>Rockville, MD</i>	prevention of influenza virus infections	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	CruCell <i>Leiden, The Netherlands</i>	prevention of influenza virus infections	Phase II www.cruccell.com
influenza virus vaccine (Fluad)	Novartis Vaccines <i>Cambridge, MA</i>	prevention of influenza virus infections	Phase III (888) 669-6682
influenza virus vaccine intranasal	Vaxin <i>Birmingham, AL</i>	influenza virus infections	Phase I (205) 909-3751
influenza virus vaccine (Optaflu)	Novartis Vaccines <i>Cambridge, MA</i>	influenza virus infections	Phase III (888) 669-6682
interferon-alpha-n3 (low-dose oral)	Hemispherx Biopharma <i>Philadelphia, PA</i>	influenza virus infections	Phase I (215) 988-0080
INV102	Inverseon <i>San Francisco, CA</i>	asthma	Phase II completed (415) 440-7400



## LUNG/RESPIRATORY DISORDERS

Product Name	Company	Indication	Development Status
JNJ-32729463	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	community-acquired pneumonia	Phase II (800) 817-5286
JNJ-39758979	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	asthma	Phase II (800) 817-5286
JNJ-40929837	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	asthma	Phase II (800) 817-5286
laninamivir	Biota <i>Victoria, Australia</i> Daiichi Sankyo <i>Parsippany, NJ</i>	influenza virus infections	Phase I (973) 944-2600
LAS 100977 (LABA)	Almirall <i>Vilvoorde, Belgium</i> Forest Laboratories <i>New York, NY</i>	asthma, COPD	Phase II (800) 947-5227
levosalbutamol/ ipratropium inhalation solution	Sunovion <i>Marlborough, MA</i>	COPD	Phase II (508) 481-6700
LIQ-001	Liquidia Technologies <i>Rsch. Triangle Park, NC</i>	influenza virus infections	Phase I (888) 825-5249
losmapimod	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD (see also psychiatric)	Phase II (888) 825-5249
masitinib	AB Science USA <i>Short Hills, NJ</i>	asthma	Phase III (973) 218-2437
MEDI-528	AstraZeneca <i>Wilmington, DE</i> Ligand Pharmaceuticals <i>La Jolla, CA</i> MedImmune <i>Gaithersburg, MD</i>	asthma	Phase II (800) 236-9933 (858) 550-7500 (301) 398-0000
MEDI-550 (influenza vaccine)	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	prevention of pandemic influenza	Phase I (800) 236-9933 (301) 398-0000
MEDI-557 (RSV mAb extended half-life)	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	COPD	Phase I (800) 236-9933 (301) 398-0000
MEDI-563 (anti-IL-5R mAb)	AstraZeneca <i>Wilmington, DE</i> MedImmune <i>Gaithersburg, MD</i>	asthma	Phase II (800) 236-9933 (301) 398-0000

## LUNG/RESPIRATORY DISORDERS

Product Name	Company	Indication	Development Status
MEDI-2338	AstraZeneca Wilmington, DE MedImmune Gaithersburg, MD	COPD	Phase I (800) 236-9933 (301) 398-0000
MEDI-3250 (influenza vaccine)	AstraZeneca Wilmington, DE MedImmune Gaithersburg, MD	seasonal influenza	Phase III (800) 236-9933 (301) 298-0000
mepolizumab	GlaxoSmithKline Rsch. Triangle Park, NC	severe asthma	Phase II (888) 825-5249
MK-0476C (montelukast/ mometasone)	Merck Whitehouse Station, NJ	asthma	Phase II (800) 672-6372
N6002	N30 Pharmaceuticals Boulder, CO	acute asthma	Phase I/II (720) 945-7700
navarixin (SCH 527123)	Merck Whitehouse Station, NJ	COPD	Phase II (800) 672-6372
NB-1008	NanoBio Ann Arbor, MI	prevention of influenza virus infections	Phase I completed (734) 302-4000
nitazoxanide	Romark Laboratories Tampa, FL	influenza virus infections	Phase II/III (813) 282-8544
NVA237 (glycopyrrolate inhalation)	Novartis Pharmaceuticals East Hanover, NJ	COPD	Phase III (888) 669-6682
omadacycline (PTK796)	Novartis Pharmaceuticals East Hanover, NJ Paratek Pharmaceuticals Boston, MA	community-acquired pneumonia	Phase I (888) 669-6682 (617) 275-0040
<b>PanBlok™</b> influenza virus vaccine	Protein Sciences Meriden, CT	prevention of influenza A virus H5N1 subtype	Phase I/II (800) 488-7099
peramivir	BioCryst Pharmaceuticals Birmingham, AL	acute influenza	Phase III (205) 444-4600
PF-4764793 (PF-00241939)	Pfizer New York, NY	asthma	Phase I (860) 732-5156
PF-00610355	Pfizer New York, NY	COPD	Phase II (860) 732-5156
PF-03526299	Pfizer New York, NY	asthma	Phase I (860) 732-5156
PF-03635659	Pfizer New York, NY	COPD	Phase II (860) 732-5156
PF-03715455	Pfizer New York, NY	COPD	Phase I (860) 732-5156
PF-03893787	Pfizer New York, NY	asthma	Phase I (860) 732-5156

## LUNG/RESPIRATORY DISORDERS

Product Name	Company	Indication	Development Status
PF-05212372 (PLA-950)	Pfizer New York, NY	asthma	Phase I (860) 732-5156
PGX-100	ParinGenix Tucson, AZ	COPD	Phase II
PH-797804	Pfizer New York, NY	COPD	Phase II (860) 732-5156
<b>Preflucel™</b> seasonal influenza virus vaccine	Baxter International Deerfield, IL	prevention of influenza virus infections	Phase III (800) 422-9837
<b>Prochymal®</b> (remestemcel-L)	Osiris Therapeutics Columbia, MD	COPD (see also autoimmune)	Phase II (443) 545-1800
<i>Pseudomonas aeruginosa</i> antibody fragment	sanofi-aventis Bridgewater, NJ	prevention of ventilator-associated pneumonia	Phase I (800) 633-1810
PT001 (glycopyrrolate inhalation aerosol)	Pearl Therapeutics Redwood City, CA	COPD	Phase II (650) 305-2600
PT003 (glycopyrrolate/ formoterol inhalation aerosol)	Pearl Therapeutics Redwood City, CA	COPD	Phase II (650) 305-2600
PT005 (formoterol inhalation aerosol)	Pearl Therapeutics Redwood City, CA	COPD	Phase I/II completed (650) 305-2600
PUR003	Pulmatrix Lexington, MA	asthma, treatment of influenza virus infections	Phase I (781) 357-2333
PUR118	Pulmatrix Lexington, MA	influenza virus infections	Phase I (781) 357-2333
QAW039	Novartis Pharmaceuticals East Hanover, NJ	asthma	Phase II (888) 669-6682
QAX576	Novartis Pharmaceuticals East Hanover, NJ	asthma	Phase II (888) 669-6682
QGE031	Novartis Pharmaceuticals East Hanover, NJ	asthma	Phase I (888) 669-6682
QVA149 (glycopyrrolate/ indacaterol)	Novartis Pharmaceuticals Morris Plains, NJ	COPD	Phase II (888) 669-6682
R(+) zileuton	Cornerstone Therapeutics Cary, NC	asthma	Phase I completed (888) 466-6505
radezolid	Rib-X Pharmaceuticals New Haven, CT	community-acquired pneumonia	Phase II (203) 624-5606
<b>Relenza®</b> zanamivir intravenous	GlaxoSmithKline Rsch. Triangle Park, NC	influenza	Phase II (888) 825-5249

## LUNG/RESPIRATORY DISORDERS

Product Name	Company	Indication	Development Status
<b>Relovair™</b> vilanterol/ fluticasone furoate	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	asthma, COPD	Phase III (888) 669-6682
reslizumab (CEP-38072)	Cephalon <i>Frazer, PA</i>	asthma	Phase III (610) 344-0200
<b>Restanza™</b> cethromycin	Advanced Life Sciences <i>Woodridge, IL</i>	community-acquired pneumonia	Phase III (630) 739-6744
RG3637 (lebrikizumab)	Genentech <i>South San Francisco, CA</i>	asthma	Phase II (800) 626-3553
RG4930 (OX40LhuMAb)	Roche <i>Nutley, NJ</i>	asthma	Phase II (973) 235-5000
RG7185 (CRTH2 antagonist)	Roche <i>Nutley, NJ</i>	COPD	Phase I (973) 235-5000
RNS60	Revalesio <i>Tacoma, WA</i>	asthma	Phase I/II www.revalesio.com
RX-10001	Resolvix <i>Bedford, MA</i>	asthma (see also arthritis/musculoskeletal)	Phase I (781) 541-5045
salbutamol dry-powder inhalation	Teva Pharmaceuticals North America <i>North Wales, PA</i>	asthma	Phase III (215) 591-3000
SAR231893 (anti-IL4 mAb)	sanofi-aventis <i>Bridgewater, NJ</i>	asthma	Phase II (800) 633-1610
solithromycin	Cempra Pharmaceuticals <i>Chapel Hill, NC</i>	community-acquired pneumonia	Phase II (919) 467-1716
<b>Spiriva®</b> <b>HandiHaler®</b> tiotropium bromide	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	asthma (adjunctive therapy) ----- asthma	Phase III (800) 243-0127 ----- Phase II (800) 243-0127
<i>Streptococcus pneumoniae</i> vaccine	sanofi pasteur <i>Swiftwater, PA</i>	pneumonia	Phase I (800) 822-2463
TC-6987	Targacept <i>Winston-Salem, NC</i>	asthma	Phase II (336) 480-2100
TD-4208	Theravance <i>South San Francisco, CA</i>	COPD	Phase I completed (650) 808-6000
tetomilast (OPC-65335)	Otsuka America Pharmaceutical <i>Rockville, MD</i>	COPD	Phase II (800) 562-3974
VAX-102	VaxInnate <i>Cranbury, NJ</i>	prevention of influenza A virus infections	Phase I/II (609) 860-2260
VAX-125	VaxInnate <i>Cranbury, NJ</i>	influenza A virus infections	Phase II (609) 860-2260
VAX-128	VaxInnate <i>Cranbury, NJ</i>	prevention of influenza A virus H1N1 subtype	Phase I (609) 860-2260

## LUNG/RESPIRATORY DISORDERS

Product Name	Company	Indication	Development Status
<b>Veldona®</b> interferon-alpha lozenge	Amarillo Biosciences <i>Amarillo, TX</i>	COPD (see also arthritis/musculoskeletal, obstetric/gynecologic)	Phase II (806) 376-1741
VGX-3400	Inovio Pharmaceuticals <i>Blue Bell, PA</i>	prevention of influenza A virus H5N1 subtype	Phase I (267) 440-4200
<b>Vibativ™</b> telavancin	Theravance <i>South San Francisco, CA</i>	nosocomial pneumonia	application submitted (877) 275-8479
vilanterol (GSK642444)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase III (888) 669-6682
		asthma	Phase II (888) 669-6682
zabofloxacin	IASO Pharma <i>San Diego, CA</i>	community-acquired pneumonia	Phase II (888) 648-8885
zileuton intravenous	Cornerstone Therapeutics <i>Cary, NC</i>	acute asthma	Phase II (888) 466-6505
<b>Zithromax®</b> azithromycin	Pfizer <i>New York, NY</i>	asthma	Phase III completed (860) 732-5156
<b>Zyflo®</b> zileuton oral	Cornerstone Therapeutics <i>Cary, NC</i>	COPD	Phase III (888) 466-6505

## NEUROLOGIC DISORDERS

Product Name	Company	Indication	Development Status
18-flutemetamol (PET imaging agent)	GE Healthcare <i>Waukesha, WI</i>	Alzheimer's disease diagnosis	Phase III <a href="http://www.gehealthcare.com">www.gehealthcare.com</a>
AAB-002	Janssen Alzheimer Immunotherapy <i>South San Francisco, CA</i> Pfizer <i>New York, NY</i>	Alzheimer's disease	Phase 0 (800) 817-5286 (860) 732-5156
AAB-003 (PF-05236812)	Janssen Alzheimer Immunotherapy <i>South San Francisco, CA</i> Pfizer <i>New York, NY</i>	Alzheimer's disease	Phase I (800) 817-5286 (860) 732-5156
AAD-2004	AmKor Pharma <i>Sammamish, WA</i> Neurotech Pharmaceuticals <i>Seoul, South Korea</i>	Alzheimer's disease	Phase I <a href="http://www.amkorpharma.com">www.amkorpharma.com</a>
ABT-126	Abbott Laboratories <i>Abbott Park, IL</i>	Alzheimer's disease	Phase II (847) 937-6100
ABT-288	Abbott Laboratories <i>Abbott Park, IL</i>	Alzheimer's disease	Phase II (847) 937-6100
ABT-384	Abbott Laboratories <i>Abbott Park, IL</i>	Alzheimer's disease	Phase II (847) 937-6100

## NEUROLOGIC DISORDERS

Product Name	Company	Indication	Development Status
ACC-001 (PF-05236806)	Janssen Alzheimer Immunotherapy <i>South San Francisco, CA</i> Pfizer <i>New York, NY</i>	Alzheimer's disease	Phase II (800) 817-5286 (860) 732-5156
ACC-002	Janssen Alzheimer Immunotherapy <i>South San Francisco, CA</i> Pfizer <i>New York, NY</i>	Alzheimer's disease	Phase 0 (800) 817-5286 (860) 732-5156
AD02 affitope vaccine	Affiris <i>Vienna, Austria</i> GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	Alzheimer's disease	Phase II (888) 825-5249
AD03 affitope vaccine	Affiris <i>Vienna, Austria</i> GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	Alzheimer's disease	Phase I (888) 669-6682
<b>Amyvid™</b> florbetapir F 18 (PET imaging agent)	Avid Radiopharmaceuticals <i>Philadelphia, PA</i> Eli Lilly <i>Indianapolis, IN</i>	Alzheimer's disease diagnosis	application submitted (215) 298-0700 (800) 545-5979
ARC029 (nilvadipine)	Archer Pharmaceuticals <i>Sarasota, FL</i>	Alzheimer's disease	Phase I (941) 755-6644
ARC031	Archer Pharmaceuticals <i>Sarasota, FL</i>	Alzheimer's disease	Phase I (941) 755-6644
ARC031-SR (sustained-release)	Archer Pharmaceuticals <i>Sarasota, FL</i>	Alzheimer's disease	Phase I (941) 755-6644
ASP 0777	Astellas Pharma US <i>Deerfield, IL</i>	Alzheimer's disease	Phase I (800) 695-4321
AV965	Avera Pharmaceuticals <i>San Diego, CA</i>	Alzheimer's disease	Phase I (858) 847-0650
AVN 101	Avineuro Pharmaceuticals <i>San Diego, CA</i>	Alzheimer's disease (see also psychiatric)	Phase II (858) 436-1537
AVN 322	Avineuro Pharmaceuticals <i>San Diego, CA</i>	Alzheimer's disease	Phase I (858) 436-1537
AVN 397	Avineuro Pharmaceuticals <i>San Diego, CA</i>	Alzheimer's disease (see also psychiatric)	Phase II (858) 436-1537
AZ-001	Alexza Pharmaceuticals <i>Palo Alto, CA</i>	migraine	Phase II completed (650) 687-3900
AZD1446 (TC-6683) alpha4/beta2 neuronal nicotinic receptor agonist	AstraZeneca <i>Wilmington, DE</i> Targacept <i>Winston-Salem, NC</i>	Alzheimer's disease	Phase II (800) 236-9933 (336) 480-2100
AZD5213 (H3AN)	AstraZeneca <i>Wilmington, DE</i>	Alzheimer's disease	Phase I (800) 236-9933

## NEUROLOGIC DISORDERS

Product Name	Company	Indication	Development Status
BACE1 protein inhibitor	Ligand Pharmaceuticals <i>San Diego, CA</i> Merck <i>Whitehouse Station, NJ</i>	Alzheimer's disease	Phase I (858) 550-7500 (800) 672-6372
BACE1 protein inhibitor (LY2434074)	Eli Lilly <i>Indianapolis, IN</i>	Alzheimer's disease	Phase I (800) 545-5979
BAN2401 (anti-beta amyloid antibody)	Eisai <i>Woodcliff Lake, NJ</i>	Alzheimer's disease	Phase I (888) 422-4743
bapineuzumab (AAB-001)	Janssen Alzheimer Immunotherapy <i>South San Francisco, CA</i> Pfizer <i>New York, NY</i>	Alzheimer's disease (intravenous) (Fast Track) ----- Alzheimer's disease (subcutaneous)	Phase III (800) 817-5286 (860) 732-5156  Phase II (800) 817-5286 (860) 732-5156
BAY 85-8101 (PET imaging agent)	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	Alzheimer's disease diagnosis (see also autoimmune)	Phase I completed (888) 842-2937
BAY 94-9172 (florbetaben) (PET imaging agent)	Avid Radiopharmaceuticals <i>Philadelphia, PA</i> Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	Alzheimer's disease diagnosis	Phase III (215) 298-0700 (888) 842-2937
BGG492	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	migraine	Phase II completed (888) 669-6682
BI 44370	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	migraine	Phase II completed (800) 243-0127
bisnorcymserine (BNC)	QR Pharma <i>Radnor, PA</i>	Alzheimer's disease	Phase I (484) 253-2296
CAD106	CytosBiotechnology <i>Postfach, Switzerland</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	Alzheimer's disease	Phase II (888) 669-6682
CERE-110 (gene therapy)	Ceregene <i>San Diego, CA</i>	Alzheimer's disease	Phase II (858) 458-8800
CHF 5074	Chiesi Pharmaceuticals <i>Rockville, MD</i>	Alzheimer's disease	Phase I (301) 424-2661
COL-144	CoLucid Pharmaceuticals <i>Rsch. Triangle Park, NC</i>	migraine	Phase II completed (919) 806-4304
CTS-21166	Astellas Pharma US <i>Deerfield, IL</i> CoMentis <i>South San Francisco, CA</i>	Alzheimer's disease	Phase I (800) 695-4321 (650) 359-2600

## NEUROLOGIC DISORDERS

Product Name	Company	Indication	Development Status
CX-717	Cortex Pharmaceuticals <i>Irvine, CA</i>	Alzheimer's disease	Phase II (949) 727-3157
cyclobenzaprine extended-release	Cephalon <i>Frazer, PA</i>	migraine	Phase III (610) 344-0200
davunetide intranasal (AL-108)	Allon Therapeutics <i>Vancouver, Canada</i>	Alzheimer's disease	Phase II (604) 736-0634
docosahexaenoic acid	Martek Biosciences <i>Columbia, MD</i>	Alzheimer's disease	Phase III (410) 740-0081
DSP-8658	Sunovion <i>Marlborough, MA</i>	Alzheimer's disease	Phase I (508) 481-6700
E2609	Eisai <i>Woodcliff Lake, NJ</i>	Alzheimer's disease	Phase I (888) 274-2378
EGb 761	Ipsen <i>Milford, MA</i>	Alzheimer's disease	Phase III (508) 478-8900
ELND005	Elan Pharmaceuticals <i>South San Francisco, CA</i> Transition Therapeutics <i>Toronto, Canada</i>	Alzheimer's disease (Fast Track)	Phase II completed (650) 877-0900 (416) 260-7770
EVP-0334	EnVivo Pharmaceuticals <i>Watertown, MA</i>	Alzheimer's disease	Phase I completed (617) 225-4250
EVP-6124	EnVivo Pharmaceuticals <i>Watertown, MA</i>	Alzheimer's disease	Phase II (617) 225-4250
<b>Exebryl-1®</b>	ProteoTech <i>Kirkland, WA</i>	Alzheimer's disease	Phase I (425) 823-0400
<b>Gammagard S/D™</b> immune globulin (IVIG)	Baxter Healthcare <i>Deerfield, IL</i>	Alzheimer's disease	Phase III (800) 422-9837
gamma secretase inhibitor (BMS-708163)	Bristol-Myers Squibb <i>Princeton, NJ</i>	prodromal Alzheimer's disease	Phase II (212) 546-4000
GSK239512 (histamine H3 antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	Alzheimer's disease (see also psychiatric)	Phase II completed (888) 669-6682
GSK742457	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	Alzheimer's disease (see also psychiatric)	Phase II (888) 669-6682
GSK933776 (beta amyloid mAb)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	Alzheimer's disease	Phase I (888) 825-5249
GSK2315698 (serum amyloid P [SAP] component inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	Alzheimer's disease	Phase I (888) 669-6682
HPP-854	High Point Pharmaceuticals <i>High Point, NC</i>	Alzheimer's disease	Phase I (336) 841-0300



## NEUROLOGIC DISORDERS

Product Name	Company	Indication	Development Status
immune globulin high dose	Octapharma USA <i>Hoboken, NJ</i>	Alzheimer's disease	Phase II completed (201) 604-1130
intravenous normal human immunoglobulin	Grifols USA <i>Los Angeles, CA</i>	Alzheimer's disease	in clinical trials (888) 474-3657
latrepirdine (dimebolin)	Medivation <i>San Francisco, CA</i> Pfizer <i>New York, NY</i>	early-stage Alzheimer's disease	Phase III (415) 543-3470 (860) 732-5156
		Alzheimer's disease (combination therapy)	Phase I (415) 543-3470 (860) 732-5156
<b>Levadex™</b> dihydroergotamine inhalation	Allergan <i>Irvine, CA</i> MAP Pharmaceuticals <i>Mountain View, CA</i>	migraine	Phase III (800) 433-8871 (650) 386-3100
LNK-754	LINK Medicine <i>Cambridge, MA</i>	Alzheimer's disease	Phase I (617) 583-1060
Lu AE58054	Lundbeck <i>Deerfield, IL</i>	Alzheimer's disease	Phase II (800) 455-1141
LY451395	Eli Lilly <i>Indianapolis, IN</i>	agitation in Alzheimer's disease	Phase II (800) 545-5979
LY2300559	Eli Lilly <i>Indianapolis, IN</i>	migraine prevention	Phase II (800) 545-5979
LY2886721	Eli Lilly <i>Indianapolis, IN</i>	Alzheimer's disease	Phase I (800) 545-5979
MCD-386CR	Mithridion <i>Madison, WI</i>	Alzheimer's disease	Phase I (608) 443-2432
MK-0974 (telcagepant)	Merck <i>Whitehouse Station, NJ</i>	migraine prevention	Phase III (800) 672-6372
MK-2918	Merck <i>Whitehouse Station, NJ</i>	migraine	in clinical trials (800) 672-6372
MK-3328 (PET imaging agent)	Merck <i>Whitehouse Station, NJ</i>	Alzheimer's disease diagnosis	Phase I (800) 672-6372
NGX-426	Raptor Pharmaceutical <i>Novato, CA</i>	migraine	Phase I (877) 727-8679
NIC5-15	Humanetics <i>Eden Prairie, MN</i>	Alzheimer's disease	Phase II completed (952) 937-7660
NSA-789	Pfizer <i>New York, NY</i>	Alzheimer's disease	Phase I (860) 732-5156
NXN-188	NeurAxon <i>Mississauga, Canada</i>	migraine	Phase II (416) 673-6697
<b>Oxigon™</b> indolepropionic acid derivative	Intellect Neurosciences <i>New York, NY</i>	Alzheimer's disease	Phase I completed (212) 448-9300

## NEUROLOGIC DISORDERS

Product Name	Company	Indication	Development Status
PF-04360365 (ponezumab)	Pfizer New York, NY	Alzheimer's disease	Phase II (860) 732-5156
PF-04427429	Pfizer New York, NY	migraine	Phase I (860) 732-5156
PF-04494700	Pfizer New York, NY	Alzheimer's disease	Phase II (860) 732-5156
PF-04995274	Pfizer New York, NY	Alzheimer's disease	Phase I (860) 732-5156
PF-05212377 (SAM-760)	Pfizer New York, NY	Alzheimer's disease	Phase I (860) 732-5156
<b>Posiphen™</b> R-phenserine	QR Pharma Radnor, PA	Alzheimer's disease	Phase II (484) 253-2296
PRX-3140	Nanotherapeutics Alachua, FL	Alzheimer's disease	Phase II (386) 462-9663
RG1450 (gantenerumab)	Roche Nutley, NJ	Alzheimer's disease	Phase II (973) 235-5000
RG1662	Roche Nutley, NJ	Alzheimer's disease	Phase I (973) 235-5000
RG3487 (nicotinic alpha-7 receptor agonist)	Roche Nutley, NJ	Alzheimer's disease	Phase II (973) 235-5000
RG7412 (anti-Abeta)	Genentech South San Francisco, CA	Alzheimer's disease	Phase I (800) 626-3553
RVX-208	Resverlogix Calgary, Canada	Alzheimer's disease	Phase I (403) 254-9252
SAM-531 (PF-05212365)	Pfizer New York, NY	Alzheimer's disease	Phase II (860) 732-5156
SAR110894 (H3 antagonist)	sanofi-aventis Bridgewater, NJ	Alzheimer's disease	Phase II (800) 633-1610
solanezumab	Eli Lilly Indianapolis, IN	Alzheimer's disease	Phase III (800) 545-5979
<b>Sprix®</b> ketorolac intranasal	Luitpold Pharmaceuticals Shirley, NY	migraine	Phase II completed (631) 924-4000
ST-101	Sonexa Therapeutics San Diego, CA	Alzheimer's disease	Phase II (858) 356-6250
T-817MA	Toyama Chemical Tokyo, Japan	Alzheimer's disease	Phase II
TC-5619	Targacept Winston-Salem, NC	Alzheimer's disease	Phase I (336) 480-2100
TD-5108 (velusetrag)	Theravance South San Francisco, CA	Alzheimer's disease	Phase II (877) 275-8479
TD-8954	Theravance South San Francisco, CA	Alzheimer's disease	Phase I (877) 275-8479

## NEUROLOGIC DISORDERS

Product Name	Company	Indication	Development Status
tezampanel	Raptor Pharmaceutical Novato, CA	migraine	Phase II completed (877) 727-8679
UB-311 vaccine	United Biomedical Hauppauge, NY	mild to moderate Alzheimer's disease	Phase I (631) 273-2828
V950	Merck Whitehouse Station, NJ	Alzheimer's disease	Phase I (800) 672-6372
<b>Zelrix™</b> sumatriptan transdermal	NuPathe Conshohocken, PA	migraine	application submitted (484) 567-0130

## OBSTETRIC/GYNECOLOGIC CONDITIONS

Product Name	Company	Indication	Development Status
ADX-415	Shionogi Florham Park, NJ	hot flashes	Phase I/II (973) 966-6900
afimoxifene	ASCEND Therapeutics Herndon, VA	cyclic breast pain, reduction of increased breast density that can obscure mammogram readings (see also cancer)	Phase II (703) 471-4744
AG200-15 (ethinyl estradiol/ levonorgestrel transdermal)	Agile Therapeutics San Jose, CA	contraception	Phase III (408) 284-4000
AG900 (transdermal levonorgestrel)	Agile Therapeutics San Jose, CA	contraception	in clinical trials (408) 284-4000
<b>Alferon N LDO®</b> interferon-alfa-n3	Hemispherx Biopharma Philadelphia, PA	human papillomavirus infections	Phase I/II (215) 988-0080
<b>Angeliq®</b> estradiol/ drospirenone	Bayer HealthCare Pharmaceuticals Wayne, NJ	contraception	Phase II (888) 842-2937
<b>Angeliq®</b> <b>Low Dose</b> estradiol/ drospirenone	Bayer HealthCare Pharmaceuticals Wayne, NJ	menopause syndrome	Phase III (888) 842-2937
<b>Aprala™</b> bazedoxifene/ conjugated estrogens	Ligand Pharmaceuticals San Diego, CA Pfizer New York, NY	menopausal vasomotor symptoms (see also arthritis/musculoskeletal)	Phase III completed (858) 550-7500 (860) 732-5156
AUS-131	Ausio Pharmaceuticals Cincinnati, OH	vasomotor symptoms (see also arthritis/musculoskeletal)	Phase II (513) 731-1600
BAY 86-5016/ FC patch low (ethinyl estradiol/ gestodene transdermal)	Bayer HealthCare Pharmaceuticals Wayne, NJ	contraception	Phase III (888) 842-2937

## OBSTETRIC/GYNECOLOGIC CONDITIONS

Product Name	Company	Indication	Development Status
BAY 98-7078 (estradiol valerate/ levomefolate)	Bayer HealthCare Pharmaceuticals Wayne, NJ	contraception	Phase I (888) 842-2937
bedoradrine (MN-221)	MediciNova San Diego, CA	preterm labor (see also lung/respiratory)	Phase I completed (858) 373-1500
BGS649	Novartis Pharmaceuticals East Hanover, NJ	endometriosis	Phase II (888) 669-6682
bremelanotide subcutaneous	Palatin Technologies Cranbury, NJ	female sexual dysfunction	Phase I (609) 495-2200
C31G	Adamis Pharmaceuticals Del Mar, CA	contraception	Phase III (858) 401-3984
CDB-4124	Repros Therapeutics The Woodlands, TX	uterine leiomyoma	Phase I/II (281) 719-3400
corifollitropin alfa injection (SCH 900962)	Merck Whitehouse Station, NJ	infertility	Phase III (800) 672-6372
CTP-347	Concert Pharmaceuticals Lexington, MA	hot flashes	Phase I (781) 860-0045
CTV-05	Osel Santa Clara, CA	bacterial vaginosis (see also kidney/urologic)	Phase II completed (408) 986-0012
DR-102 (ethinylestradiol/ desogestrel)	Teva Pharmaceuticals USA North Wales, PA	contraception	Phase III (215) 591-3000
<b>ella</b> ® ulipristal vaginal (continuous)	HRA Pharma New York, NY Watson Pharmaceuticals Parsippany, NJ	contraception	Phase III (212) 679-2945 (800) 900-1644
estradiol/ elcometrine transdermal gel	Antares Pharma Ewing, NJ Population Council New York, NY	contraception	Phase II (609) 359-3020
estradiol/ elcometrine vaginal ring	Population Council New York, NY Watson Pharmaceuticals Corona, CA	contraception	Phase III (800) 249-5499
estradiol/ norgestrol monophasic (NOMAC/E2) (SCH 900121)	Merck Whitehouse Station, NJ	contraception	Phase III completed (800) 672-6372
etonogestrel- releasing intrauterine system (SCH 900342)	Merck Whitehouse Station, NJ	contraception	Phase II (800) 672-6372
<b>Femprox</b> ® alprostadil topical	Apricus Biosciences San Diego, CA	female sexual dysfunction	Phase II (858) 222-8041

## OBSTETRIC/GYNECOLOGIC CONDITIONS

Product Name	Company	Indication	Development Status
FP1198	FemmePharma Global Healthcare Wayne, PA	breast pain	Phase II (610) 995-0801
GnRH transdermal patch	Vyteris Fair Lawn, NY	female infertility	Phase II (201) 703-2299
GS-9191	Graceway Pharmaceuticals Bristol, TN	human papillomavirus infections	Phase I completed (800) 328-0255
GSK221149 (retosiban)	GlaxoSmithKline Rsch. Triangle Park, NC	preterm labor	Phase II (888) 825-5249
GSK232802 (SERM)	GlaxoSmithKline Rsch. Triangle Park, NC	vasomotor symptoms	Phase II completed (888) 825-5249
GW-05 (metronidazole vaginal gel)	Graceway Pharmaceuticals Bristol, TN	bacterial vaginosis	Phase II (800) 328-0255
human papillomavirus vaccine (HPV-16)	Novavax Rockville, MD	human papillomavirus infections	Phase II (240) 268-2000
hyperglycosylated follicle-stimulating hormone (FSH)	EMD Serono Rockland, MA	female infertility	Phase II (800) 283-8088
isavuconazole	Astellas Pharma US Deerfield, IL	candidiasis	Phase III
levonorgestrel intrauterine ultra low-dose (LCS/ULD LNG)	Bayer HealthCare Pharmaceuticals Wayne, NJ	contraception	Phase III (888) 842-2937
<b>LibiGel®</b> testosterone gel	BioSante Pharmaceuticals Lincolnshire, IL	female sexual dysfunction	Phase III (847) 478-0500
<b>LibiGel-E/T™</b> estradiol/ testosterone topical gel	BioSante Pharmaceuticals Lincolnshire, IL	female sexual dysfunction, hot flashes	Phase II (847) 478-0500
<b>Mesafem™</b> paroxetine low-dose	Noven Pharmaceuticals Miami, FL	menopausal vasomotor symptoms	Phase III (305) 253-5099
metreleptin ( <b>Orphan Drug</b> )	Amylin Pharmaceuticals San Diego, CA	amenorrhea (see also autoimmune)	Phase II (858) 552-2200
MF-101	Bionovo Emeryville, CA	vasomotor symptoms	Phase II (510) 601-2000
misoprostol controlled-release insert	Cytokine PharmaSciences King of Prussia, PA	labor induction	Phase III (859) 371-6383
<b>Natazia™</b> estradiol valerate/ dienogest	Bayer HealthCare Pharmaceuticals Wayne, NJ	metrorrhagia	application submitted (888) 842-2937

## OBSTETRIC/GYNECOLOGIC CONDITIONS

Product Name	Company	Indication	Development Status
NBI-56418 (elagolix)	Abbott Laboratories <i>Abbott Park, IL</i> Neurocrine Biosciences <i>San Diego, CA</i>	endometriosis	Phase II completed (847) 937-6100 (858) 617-7600
		uterine leiomyoma	Phase I (847) 937-6100 (858) 617-7600
ospemifene	Shionogi <i>Florham Park, NJ</i>	postmenopausal vaginal atrophy	Phase III (973) 966-6900
PH80	Pherin Pharmaceuticals <i>Los Altos, CA</i>	premenstrual syndrome	Phase II completed (650) 961-2703
<b>Pristiq</b> <sup>TM</sup> desvenlafaxine succinate	Pfizer <i>New York, NY</i>	menopausal vasomotor symptoms	application submitted (860) 732-5156
<b>Prochieve</b> <sup>®</sup> progesterone 8%	Columbia Laboratories <i>Livingston, NJ</i>	preterm labor (prevention)	Phase III (866) 566-5636
<b>Proellex</b> <sup>®</sup> telapristone	Repros Therapeutics <i>The Woodlands, TX</i>	endometriosis, uterine leiomyoma	Phase I/II (281) 719-3400
RAD1901	Radius <i>Cambridge, MA</i>	vasomotor symptoms	Phase II completed (617) 551-4700
<b>Serada</b> <sup>TM</sup> gabapentin extended-release	Depomed <i>Menlo Park, CA</i>	menopausal hot flashes	Phase III (650) 462-5900
silicone breast cohesive gel	Allergan <i>Irvine, CA</i>	breast reconstruction and augmentation	application submitted (714) 246-4500
SPL-7013	StarPharma <i>Victoria, Australia</i>	bacterial vaginosis	Phase II <a href="http://www.starpharma.com">www.starpharma.com</a>
S-PRAnt	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	uterine leiomyoma	Phase I (888) 842-2937
testosterone vaginal	Columbia Laboratories <i>Livingston, NJ</i>	uterine leiomyoma	Phase I (866) 566-5636
<b>The-Pill-Plus</b> <sup>TM</sup> triple hormone contraceptive	BioSante Pharmaceuticals <i>Lincolnshire, IL</i>	contraception	Phase III (847) 478-0500
<b>Ushercell</b> <sup>®</sup> cellulose sulfate	Polydex Pharmaceuticals <i>Toronto, Canada</i> CONRAD <i>Arlington, VA</i>	contraception	Phase II (416) 755-2231
V502	Merck <i>Whitehouse Station, NJ</i>	human papillomavirus infections	Phase II completed (800) 672-6372
V503	Merck <i>Whitehouse Station, NJ</i>	human papillomavirus infections (see also cancer)	Phase III (800) 672-6372
V505	Merck <i>Whitehouse Station, NJ</i>	human papillomavirus infections (see also cancer)	Phase II (800) 672-6372

## OBSTETRIC/GYNECOLOGIC CONDITIONS

Product Name	Company	Indication	Development Status
<b>Vaginorm™</b> prasterone vaginal	Bayer HealthCare Pharmaceuticals Wayne, NJ Endoceutics Quebec, Canada	sexual function disorders in postmenopausal women	Phase III (888) 842-2937 (418) 653-0033
		vulvovaginal atrophy in postmenopausal women	Phase III (888) 842-2937 (418) 653-0033
<b>Veldona®</b> interferon alpha lozenge (Orphan Drug)	Amarillo Biosciences Amarillo, TX	human papillomavirus infections (see also arthritis/musculoskeletal, lung/respiratory)	Phase II (806) 376-1741
VGX-3100	Inovio Pharmaceuticals Blue Bell, PA	human papillomavirus infections (see also cancer)	Phase II (267) 440-4200
WC3016 (low-dose oral contraceptive)	Warner Chilcott Rockaway, NJ	contraception	application submitted (973) 442-3200

## PSYCHIATRIC DISORDERS

Product Name	Company	Indication	Development Status
<b>Abilify®</b> aripiprazole	Bristol-Myers Squibb Princeton, NJ	depression (combination therapy)	Phase III (212) 546-4000
ABT-436	Abbott Laboratories Abbott Park, IL	anxiety, depression	Phase I (847) 937-6100
ADS-8703	Adamas Pharmaceuticals Emeryville, CA	dementia	Phase II (510) 450-3500
ADX-N05	Shionogi Florham Park, NJ	depression	Phase I (973) 966-6900
agomelatine (AGO178)	Novartis Pharmaceuticals East Hanover, NJ	depression, generalized anxiety disorder	Phase III (888) 669-6682
AVN 101	Avineuro Pharmaceuticals San Diego, CA	anxiety (see also neurologic)	Phase II (858) 436-1537
AVN 397	Avineuro Pharmaceuticals San Diego, CA	anxiety (see also neurologic)	Phase II (858) 436-1537
<b>Axona™</b>	Accera Broomfield, CO	age-associated memory impairment	Phase II (303) 439-0004
AZD2066 (metabotropic glutamate receptor 5 antagonist)	AstraZeneca Wilmington, DE	major depressive disorder	Phase II (800) 236-9933
AZD6765 (NMDA receptor antagonist)	AstraZeneca Wilmington, DE	major depressive disorder	Phase II (800) 236-9933
BCI-224 (sabcomeline)	BrainCells San Diego, CA	major depressive disorder	Phase II (858) 812-7700

## PSYCHIATRIC DISORDERS

Product Name	Company	Indication	Development Status
BCI-540 (coluracetam)	BrainCells <i>San Diego, CA</i>	anxiety, depression	Phase II (858) 812-7700
BCI-952 (buspirone/ melatonin)	BrainCells <i>San Diego, CA</i>	depression	Phase I/II (858) 812-7700
BMS-820836 (triple reuptake inhibitor)	Bristol-Myers Squibb <i>Princeton, NJ</i>	depression	Phase I (212) 546-4000
BMS-866949 (biogenic amine reuptake inhibitor)	Bristol-Myers Squibb <i>Princeton, NJ</i>	major depression	Phase I (212) 546-4000
C105	Cognition Pharmaceuticals <i>New York, NY</i>	cognitive impairment/deficit associated with multiple sclerosis	Phase II (212) 906-7071
cariprazine	Forest Laboratories <i>New York, NY</i>	major depressive disorder	Phase II (800) 947-5227
clavulanic acid	Rexahn Pharmaceuticals <i>Rockville, MD</i>	depression	Phase II (240) 268-5300
<b>Contrave®</b> naltrexone/ bupropion	Orexigen Therapeutics <i>La Jolla, CA</i> Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	depression	Phase II (858) 875-8600 (224) 554-6500
<b>Corlux™</b> mifepristone	Corcept Therapeutics <i>Menlo Park, CA</i>	depression (Fast Track)	Phase III (650) 327-3270
CP-601,927	Pfizer <i>New York, NY</i>	depression	Phase II (860) 732-5156
depression compound	Eli Lilly <i>Indianapolis, IN</i>	depression	Phase I (800) 545-5979
EB-1010	Euthymics Bioscience <i>Cambridge, MA</i>	depression	Phase II/III (617) 758-0300
EVT-101 (NMDA rector antagonist)	Evotec <i>Hamburg, Germany</i> Roche <i>Nutley, NJ</i>	depression	Phase II (973) 235-5000
EVT-103 (NMDA receptor antagonist)	Evotec <i>Hamburg, Germany</i> Roche <i>Nutley, NJ</i>	depression	Phase II (973) 235-5000
GLYX-13	Naurex <i>Evanston, IL</i>	depression	Phase I <a href="http://www.naurex.com">www.naurex.com</a>
GSK239512 (histamine H3 antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	dementia (see also neurologic)	Phase II (888) 825-5249
GSK561679 (CRF1 antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Neurocrine Biosciences <i>San Diego, CA</i>	depression, post-traumatic stress disorder, stress-related alcohol abuse	Phase II completed (888) 825-5249 (858) 617-7600



## PSYCHIATRIC DISORDERS

Product Name	Company	Indication	Development Status
GSK586529 (CRF1 antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Neurocrine Biosciences <i>San Diego, CA</i>	anxiety, depression	Phase I completed (888) 825-5249 (858) 617-7600
GSK742457	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	dementia (see also neurologic)	Phase II (888) 825-5249
INT-0004/2006	IntelGenx <i>Quebec, Canada</i>	depression	application submitted (703) 759-7460
JNJ-26489112	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	depressive disorders	Phase II (800) 817-5286
KRL-104	Krele Pharmaceuticals <i>Saddle Brook, NJ</i>	generalized anxiety disorder	in clinical trials
levomilnacipran	Forest Laboratories <i>New York, NY</i>	major depressive disorder	Phase III (800) 947-5227
lisdexamfetamine	Shire <i>Wayne, PA</i>	depression	Phase II (484) 595-8800
lithium	Columbia Northwest Pharmaceuticals <i>Bellevue, WA</i>	suicide ideation in patients with depression	Phase II (425) 453-0404
losmapimod	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	depression (see also lung/respiratory)	Phase II (888) 825-5249
LU AA21004	Lundbeck <i>Deerfield, IL</i> Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	depression, generalized anxiety disorder	Phase III (866) 337-6996 (224) 554-6500
LU AA24530	Lundbeck <i>Deerfield, IL</i> Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	depression  ----- generalized anxiety disorder	Phase II (866) 337-6996 (224) 554-6500  Phase I (866) 337-6996 (224) 554-6500
<b>Lunesta®</b> eszopiclone	Sunovion <i>Marlborough, MA</i>	generalized anxiety disorder	Phase II (508) 481-6700
LY2940094	Eli Lilly <i>Indianapolis, IN</i>	depression	Phase I (800) 545-5979
<b>Lyrica® CR</b> pregabalin (controlled-release)	Pfizer <i>New York, NY</i>	generalized anxiety disorder (adjunctive therapy) (see also arthritis/musculoskeletal)	application submitted (860) 723-5156
MK3134	Merck <i>Whitehouse Station, NJ</i>	dementia	Phase I completed (800) 672-6372
<b>Motiva™</b> nefiracetam	Neuren Pharmaceuticals <i>Bethesda, MD</i>	depression	Phase II (301) 941-1830

## PSYCHIATRIC DISORDERS

Product Name	Company	Indication	Development Status
nemifitide	Tetragenex Pharmaceuticals <i>Englewood Cliffs, NJ</i>	depression	Phase II completed (201) 408-5335
nepicastat (SYN-117)	Synosia Therapeutics <i>South San Francisco, CA</i>	post-traumatic stress disorder	Phase II (650) 244-4850
NERI (edivoxetine)	Eli Lilly <i>Indianapolis, IN</i>	depression	Phase III (800) 545-5979
NSI-189	Neuralstem <i>Rockville, MD</i>	depression	Phase I (301) 366-4960
OPC-34712	Otsuka America Pharmaceutical <i>Rockville, MD</i>	depression	Phase II (800) 562-3974
orvepitant	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	anxiety, depression, post-traumatic stress disorder	Phase II (888) 825-5249
PH94B	Pherin Pharmaceuticals <i>Redwood City, CA</i>	anxiety	Phase II (650) 568-1587
RG1578 (mGluR2 antagonist)	Roche <i>Nutley, NJ</i>	depression	Phase I (973) 235-5000
RG7090 (mGluR2 antagonist)	Roche <i>Nutley, NJ</i>	treatment-resistant depression	Phase II (973) 235-5000
RG7166 (triple reuptake inhibitor)	Roche <i>Nutley, NJ</i>	depression	Phase I (973) 235-5000
RG7351	Roche <i>Nutley, NJ</i>	depression	Phase I (973) 235-5000
rufinamide (SYN-111)	Biotie Therapies <i>South San Francisco, CA</i>	generalized anxiety disorder	Phase II completed (650) 244-4850
SEP-228432	Sunovion <i>Marlborough, MA</i>	depression	Phase I (508) 481-6700
SKL-10406	SK Drug Development <i>Fair Lawn, NJ</i>	depression	Phase I (201) 421-3800
SPN-805	Supernus Pharmaceuticals <i>Rockville, MD</i>	anxiety	Phase I (301) 838-2500
SPN-808	Supernus Pharmaceuticals <i>Rockville, MD</i>	anxiety	Phase I (301) 838-2500
SSR125543 (CRF1 antagonist)	sanofi-aventis <i>Bridgewater, NJ</i>	depression, post-traumatic stress disorder	Phase II (800) 633-1810
TC-5214	AstraZeneca <i>Wilmington, DE</i> Targacept <i>Winston-Salem, NC</i>	major depressive disorder (adjunct)	Phase III (800) 236-9933 (336) 480-2100
		major depressive disorder (monotherapy)	Phase II (800) 236-9933 (336) 480-2100

## PSYCHIATRIC DISORDERS

Product Name	Company	Indication	Development Status
TGBA01AD	Fabre-Kramer Pharmaceuticals <i>Houston, TX</i>	depression	Phase II (713) 975-6900
TGFK08AA	Fabre-Kramer Pharmaceuticals <i>Houston, TX</i>	generalized anxiety disorder	Phase II (713) 975-6900
TGW00AA	Fabre-Kramer Pharmaceuticals <i>Houston, TX</i>	generalized anxiety disorder	Phase II (713) 975-6900
TIK-101	Tikvah Therapeutics <i>Atlanta, GA</i>	phobic disorder, post-traumatic stress disorder	Phase II (404) 920-3182
traxoprodil	Pfizer <i>New York, NY</i>	depression	Phase II (860) 732-5156
<b>TriRima™</b> (CX157)	CeNeRx BioPharma <i>Cary, NC</i>	depression	Phase II (919) 234-4072
		anxiety	Phase I (919) 234-4072
VEC-162	Vanda Pharmaceuticals <i>Rockville, MD</i>	depression	Phase I (240) 599-4500
venlafaxine deuterium-substituted	Auspex Pharmaceuticals <i>Vista, CA</i>	major depressive disorder	Phase I (760) 599-1800
verucerfont	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	depression, post-traumatic stress disorder	Phase II (888) 825-5249
YKP3089	SK Drug Development Center <i>Fairlawn, NJ</i>	anxiety	Phase I (201) 421-3800

## OTHER

Product Name	Company	Indication	Development Status
AKB-6548	Akebia Therapeutics <i>Cincinnati, OH</i>	anemia	Phase II (513) 985-1920
<b>Ampligen®</b> rintatolimod	Hemispherx Biopharma <i>Philadelphia, PA</i>	chronic fatigue syndrome	application submitted (215) 988-0080
anemia protein therapy	Medgenics <i>Vienna, VA</i>	anemia	Phase I/II (646) 239-1690
AZD9773 (anti-TNF-alpha polyclonal antibody)	AstraZeneca <i>Wilmington, DE</i>	severe sepsis	Phase II (800) 236-9933
BAY 85-3934 (HIF-PH inhibitor)	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	anemia	Phase I (888) 842-2937

## OTHER

Product Name	Company	Indication	Development Status
<b>Cymbalta®</b> duloxetine	Eli Lilly <i>Indianapolis, IN</i>	chronic fatigue syndrome	Phase II/III (800) 545-5979
droxidopa	Chelsea Pharmaceuticals <i>Charlotte, NC</i>	chronic fatigue syndrome (see also arthritis/musculoskeletal)	Phase II (704) 341-1516
erythropoietin long-acting	Hanmi Pharmaceutical <i>Gyeonggi-do, South Korea</i>	anemia	Phase I www.hanmipharm.com
ferric pyro- phosphate- supplemented dialysate	Rockwell Medical Technologies <i>Wixom, MI</i>	anemia	Phase III (800) 449-3353
FG-2216	FibroGen <i>San Francisco, CA</i>	anemia	Phase II (415) 978-1200
FG-4592	FibroGen <i>San Francisco, CA</i>	anemia	Phase II (415) 978-1200
GSK1278863 (prolyl hydroxylase inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	anemia	Phase II (888) 825-5249
GSK1521498 (mu-opioid receptor inverse agonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	obsessive-eating disorder	Phase II (888) 825-5249
<b>Hematide™</b> peginesatide	Affymax <i>Palo Alto, CA</i> Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	anemia	Phase III (650) 812-8700 (224) 554-6500
<b>Hemopure®</b> hemoglobin glutamer-250 (bovine)	Biopure <i>Cambridge, MA</i>	anemia	application submitted (617) 234-6500
<b>Injectafer®</b> ferric carboxymaltose	Luitpold Pharmaceuticals <i>Shirley, NY</i>	anemia	Phase III (631) 924-4000
LY2787106	Eli Lilly <i>Indianapolis, IN</i>	anemia	Phase I (800) 545-5979
NOX-100	Medinox <i>Carlsbad, CA</i>	sepsis	Phase I/II (760) 603-8989
PHP	Apex Bioscience <i>Chapel Hill, NC</i> Curacyte <i>Munich, Germany</i>	septic shock	Phase III (919) 405-4002
sotatercept (ACE-011)	Acceleron Pharma <i>Cambridge, MA</i> Celgene <i>Summit, NJ</i>	anemia	Phase II (617) 649-9200 (908) 673-9000

## OTHER

Product Name	Company	Indication	Development Status
SUN-11031	Asubio Pharmaceuticals <i>Paramus, NJ</i>	cachexia associated with COPD, chronic heart failure, anorexia nervosa	Phase II (201) 368-5020
talactoferrin alfa	Agennix <i>Houston, TX</i>	severe sepsis	Phase II (713) 552-1091

The content of this report has been obtained through public, government and industry sources, and the Adis “R&D Insight” database based on the latest information. **Report current as of April 19, 2011.** The information in this report 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.

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## GLOSSARY

**anemia**—Condition in which the number of red blood cells or amount of hemoglobin (the protein that carries oxygen within the cell) is below normal.

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

**cervical dysplasia**—The abnormal growth of cells on the surface of the cervix. Although it is not cancer, it is considered a precancerous condition. Most cases of cervical dysplasia occur in women ages 25 to 35, although it can develop at any age. While all causes of cervical dysplasia are not known, most cases of cervical cancer and severe dysplasia are caused by infection of the cervix with a persistent, high-risk strain of human papillomavirus (HPV). Cervical dysplasia is also called **cervical intraepithelial neoplasia**, or CIN.

**cervical intraepithelial neoplasia**—Also called **cervical dysplasia**, or CIN.

**chronic fatigue syndrome**—The symptoms of this illness include debilitating fatigue, interference with the ability to concentrate, and, in some cases, a low-grade fever and swelling of the lymph nodes. Many possible causes have been implicated, but the true cause remains unknown.

**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).

**dermatomyositis**—An uncommon inflammatory disease marked by muscle weakness and a distinctive skin rash. Dermatomyositis may occur at any age, but it mostly affects adults in their late 40s to early 60s or children between 5 and 15 years of

age. Dermatomyositis affects more women than men. The signs and symptoms of dermatomyositis usually develop gradually, over weeks or months. Periods of remission, when symptoms of dermatomyositis improve spontaneously, may occur. Treatment can clear the skin rash and help patients regain muscle strength and function.

**dysmenorrhea**—Painful or difficult menstruation.

**endometriosis**—A condition in which cells lining the uterus (endometrium) are found in other parts of the pelvic cavity such as the ovaries. This results in pain and abnormal vaginal bleeding.

**fibromyalgia**—Fibromyalgia syndromes are a group of disorders of unknown cause characterized by achy pain and stiffness in soft tissues, including muscles, tendons and ligaments. Fibromyalgia (pain and stiffness) may occur throughout the body or may be restricted to certain locations. A common variation, the primary fibromyalgia syndrome, usually occurs in previously healthy young women who may be depressed, anxious, or stressed, often with interrupted and nonrestorative sleep.

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

**human papillomavirus (HPV)**—Viral agent of warts, believed to be contagious and mostly harmless, affecting only the skin's topmost layer. HPV can lead to cervical cancer.

**idiopathic thrombocytopenia purpura**—A condition that may follow a viral infection, which can trigger destruction of blood platelets by the immune system. The reduced

number of platelets may result in abnormal bleeding into the skin and from other parts of the body (purpura).

**incontinence, urinary**—Uncontrollable, involuntary urination, often due to injury or disease of the urinary tract. **Stress incontinence** refers to the involuntary escape of a small amount of urine when a person coughs, laughs, picks up a heavy package or moves excessively.

**interstitial cystitis (IC)**—A condition that results in recurring discomfort or pain in the bladder and the surrounding pelvic region. The symptoms vary from case to case and even in the same individual. People may experience mild discomfort, pressure, tenderness, or intense pain in the bladder and pelvic area. Symptoms may include an urgent need to urinate (urgency), a frequent need to urinate (frequency), or a combination of these symptoms. Pain may change in intensity as the bladder fills with urine or as it empties. Women's symptoms often get worse during menstruation. They may sometimes experience pain with vaginal intercourse.

**irritable bowel syndrome**—The most common disorder of the large intestine (also called "spastic colon") is a disturbance of involuntary muscle movement. It results in a combination of intermittent abdominal pain and irregular bowel habits.

**menorrhagia**—Excessive uterine bleeding occurring at expected intervals of the menstrual periods. Bleeding from the uterus starts on schedule but is heavier than usual and may last longer than usual. Menorrhagia may be a sign of an underlying disorder, such as hormone imbalance, endometriosis, uterine fibroids, or rarely, cancer of the uterus. Menorrhagia may cause significant anemia.

## GLOSSARY

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**metrorrhagia**—Uterine bleeding at irregular intervals, particularly between the expected menstrual periods. It may be a sign of an underlying disorder, such as hormone imbalance, endometriosis, uterine fibroids, or rarely, cancer of the uterus. Metrorrhagia may cause significant anemia.

**migraine**—A chronic disease of severe headaches resulting from an abnormal dilation of blood vessels within the brain. It can last from two hours to two days and is often accompanied by nausea, vomiting and sensitivity to noise and/or light.

**multiple sclerosis (MS)**—A chronic, often progressive disease of the central nervous system in which scattered patches of the covering of nerve fibers (myelin) in the brain and spinal cord are destroyed.

**myasthenia gravis**—A chronic autoimmune neuromuscular disease characterized by varying degrees of weakness of the skeletal (voluntary) muscles of the body. The hallmark of myasthenia gravis is muscle weakness that increases during periods of activity and improves after periods of rest. Certain muscles such as those that control eye and eyelid movement, facial expression, chewing, talking, and swallowing are often, but not always, involved in the disorder. With current therapies, most cases of myasthenia gravis are not as “grave” as the name implies. For the majority of individuals with the disease, life expectancy is not lessened by the disorder.

**nephritis**—Inflammation of the kidneys which is generally caused by an infection or an immune reaction that goes awry and injures the kidneys.

**osteoarthritis**—The most common form of joint disease, characterized by degeneration of the cartilage that lines joints and by the formation of reactive bony outgrowths at the boundary of a joint.

**osteoporosis**—The most common metabolic bone disease in older people in which a reduction in bone mass leads to fractures, especially of the vertebrae, hips and wrists.

**Phase 0**—First-in-human trials conducted in accordance with FDA’s 2006 guidance on exploratory Investigational New Drug (IND) studies designed to speed up development of promising drugs by establishing very early on whether the agent behaves in human subjects as was anticipated from preclinical studies.

**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.

**preeclampsia**—The development of hypertension with proteinuria or edema, or both, due to pregnancy or the influence of a recent pregnancy.

**premenstrual dysphoric disorder**—More commonly known as premenstrual syndrome, or PMS, this is a condition in which a variety of symptoms, including nervousness, irritability, emotional upset, depression, headaches, tissue swelling, and breast tenderness, may occur during the week to 14 days before a menstrual period begins.

**prolactinoma**—A noncancerous pituitary tumor that produces a hormone called prolactin, which results in too much prolactin in the blood.

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

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

**sepsis**—Presence of bacteria and/or their toxins in blood or tissues throughout the body.

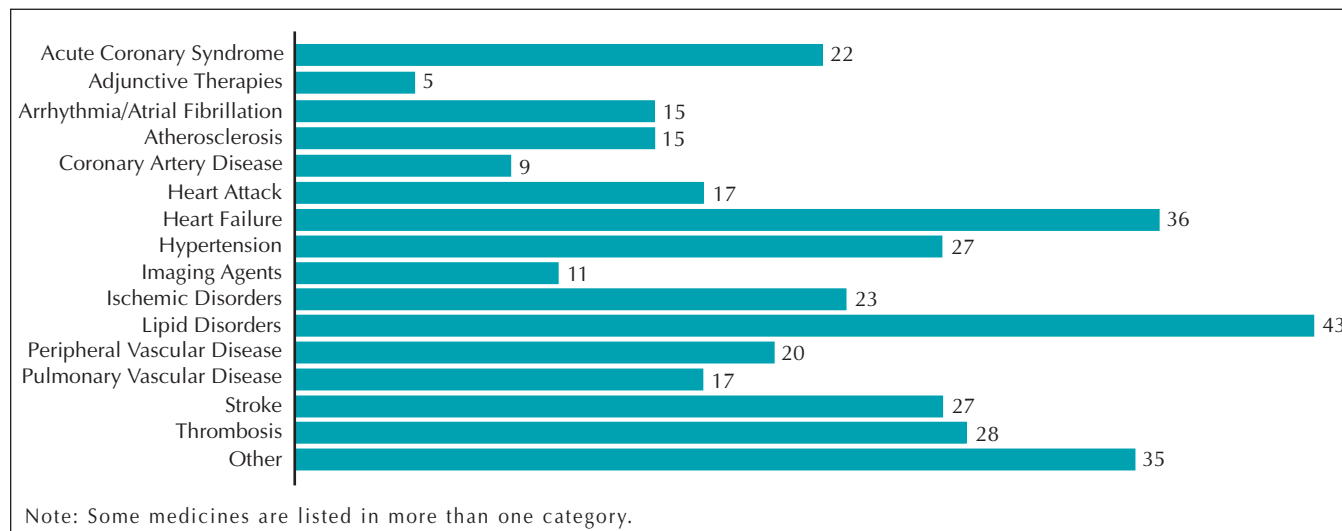
**systemic lupus erythematosus**—A chronic autoimmune disorder, affecting many systems of the body, including the kidneys and brain.

**vasomotor**—Relating to the nerves and muscles that cause the blood vessels to constrict or dilate.

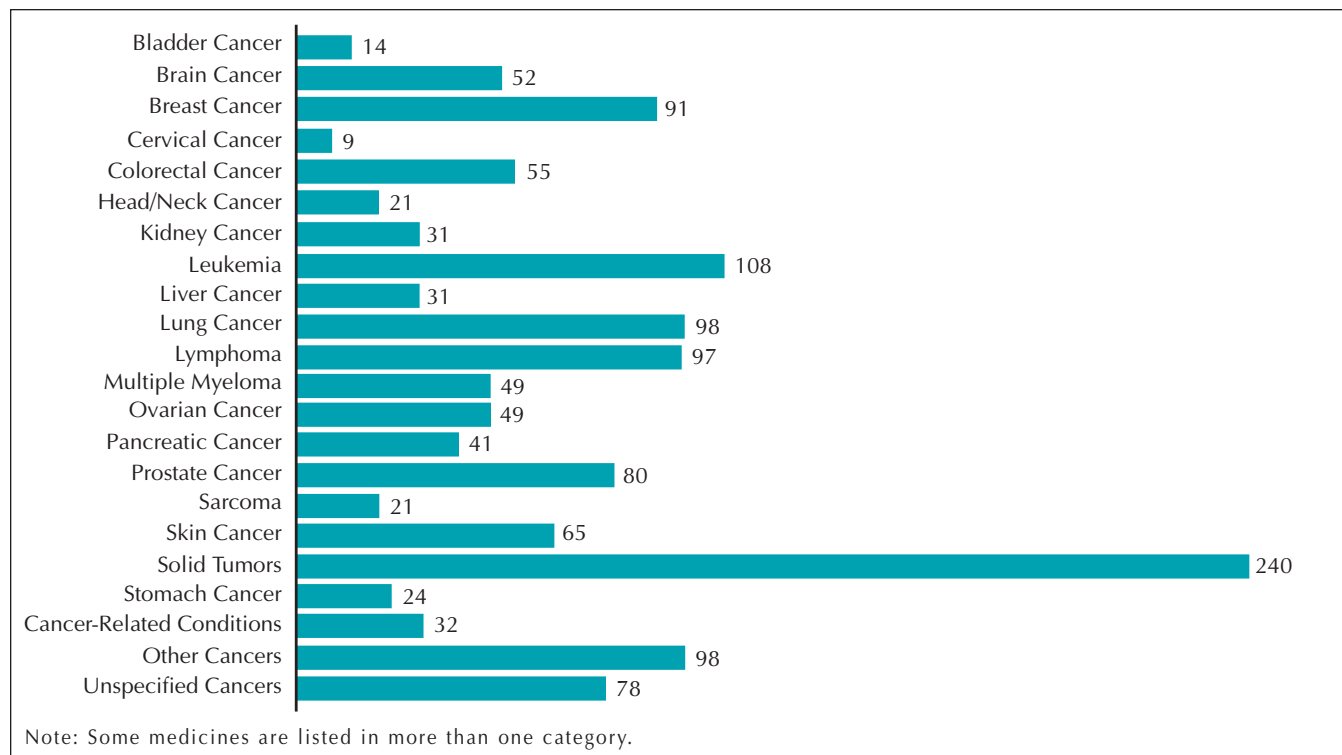
# MORE THAN 1,000 MEDICINES IN DEVELOPMENT FOR THE THREE LEADING CAUSES OF DEATH FOR AMERICAN WOMEN

The three leading causes of death among American women—heart disease, cancer and stroke—are the focus of two recent reports by the Pharmaceutical Research and Manufacturers of America (PhRMA). The reports, *Medicines in Development for Heart Disease and Stroke* and *Medicines in Development for Cancer*, list medicines in development for several types of heart disease and cancer. Following are summaries of those medicines by category listed in each of those reports. The PhRMA surveys are all available at [www.phrma.org](http://www.phrma.org).

## MEDICINES IN DEVELOPMENT FOR HEART DISEASE AND STROKE



## MEDICINES/VACCINES IN DEVELOPMENT FOR CANCER





# FACTS ABOUT DISEASES/CONDITIONS AFFECTING WOMEN IN THE UNITED STATES

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## Ten Leading Causes of Death in Women, 2007

1. Heart Disease (306,246)	6. Accidents (43,879)
2. Cancer (270,018)	7. Diabetes (35,904)
3. Cerebrovascular Diseases (81,841)	8. Influenza and Pneumonia (28,646)
4. Chronic Lower Respiratory Diseases (66,689)	9. Nephritis (23,832)
5. Alzheimer's Disease (52,832)	10. Septicemia (18,989)

Source: *National Vital Statistics Report*, Vol. 58, No. 19, May 20, 2010. National Center for Health Statistics.  
(Number in parentheses is the number of total deaths in women.)

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## Overview<sup>1</sup>

- A baby girl born in the United States in 2007 could expect to live 80.4 years; that's 5.0 years longer than a male baby, whose life expectancy would be 75.4 years.
  - In 2008, females comprised 50.7 percent of the 304 million people residing in the United States. In most age groups, women accounted for approximately half of the population, with the exception of people ages 65 and older; within that age group, women represented 58 percent of the population. The growing diversity of the U.S. population is reflected in the racial and ethnic distribution of women across age groups. African-American and Hispanic women accounted for 9.0 percent and 6.8 percent of the female population ages 65 and older, respectively, but they represented 14.1 percent and 22.4 percent of females under age 15.
  - In 2008, 63.4 percent of non-Hispanic White women reported themselves to be in excellent or very good health, compared to only 48.1 percent of Hispanic women and 48.4 percent of non-Hispanic Black women. Minority women are disproportionately affected by a number of diseases and health conditions, including asthma, diabetes, HIV/AIDS, and sexually transmitted infections.
  - Among older adults, physical disabilities are more prevalent among women than men. Overall, 68.4 percent of women and 54.4 percent of men ages 65 and older reported having an activity limitation in 2008.
- 

## Arthritis

- The term **arthritis** encompasses more than 100 diseases and conditions that affect joints, the surrounding tissues, and other connective tissues. Approximately 46 million Americans have some type of arthritis or related condition, and 60 percent of them are female.<sup>2</sup>
- **Arthritis-related disability** is more prevalent among women than men at all ages: one in four women (24.4 percent) report having a disability compared with one in five men (19.1 percent). In absolute numbers, since 1999, there has been a 22 percent increase in the number of women who attribute their disability to arthritis (6.4 million).<sup>2</sup>
- **Fibromyalgia** affects 3 million to 6 million Americans, up to 90 percent of whom are women. A recent study found that African-American women are more likely to suffer from fibromyalgia than their Caucasian counterparts.<sup>3</sup>
- **Juvenile arthritis** is one of the most common childhood diseases in the United States. Approximately 294,000 children under the age of 18 are affected by pediatric arthritis and rheumatologic conditions.<sup>2</sup> The ratio of girls to boys with polyarticular juvenile idiopathic arthritis is estimated to be up to 4.5:1; among patients with oligoarticular juvenile idiopathic arthritis, the ratio is 3:1.<sup>4</sup>
- **Osteoarthritis (OA)**, the most common form of arthritis, affects nearly 27 million Americans. Approximately 16 million OA sufferers are women, who usually develop the disorder after age 40.<sup>2</sup>

# FACTS ABOUT DISEASES/CONDITIONS AFFECTING WOMEN IN THE UNITED STATES

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## Arthritis (continued)

- **Osteoporosis** is a major public health threat for an estimated 44 million Americans, or 55 percent of people age 50 and older. Today, 10 million people already have the disease, 80 percent of whom are women. Another 34 million people have low bone density, placing them at increased risk for osteoporosis and broken bones.<sup>5</sup>
- Approximately 1.3 million American adults have **rheumatoid arthritis (RA)**, with women outnumbering men 2.5-to-1. RA usually strikes women between the ages of 25 to 50.<sup>2</sup>
- The estimated cost of **arthritis** to the economy annually is some \$128 billion.<sup>2</sup>
- In 2005, **osteoporosis**-related fractures were responsible for an estimated \$19 billion in costs. By 2025, experts predict that those costs will rise to approximately \$25.3 billion.<sup>5</sup>

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## Autoimmune Diseases

- Autoimmunity is the underlying cause of more than 100 serious, chronic illnesses, and it targets women 75 percent of the time. Altogether, **autoimmune diseases** strike women three times more than men. The female to male ratios for the following **autoimmune diseases** are: **systemic lupus erythematosus** 9:1; **antiphospholipid syndrome-secondary** 9:1; **Graves' disease** 7:1; **scleroderma** 3:1; **antiphospholipid syndrome-primary** 2:1; **autoimmune thrombocytopenic purpura (ITP)** 2:1; **multiple sclerosis** 2:1; and **myasthenia gravis** 2:1.<sup>6</sup>
- Of the 50 million Americans living with autoimmunity, 30 million are women. **Autoimmune diseases** represent the fourth largest cause of disability among women in the United States.<sup>6</sup>
- **Dermatomyositis**, an uncommon inflammatory disease marked by muscle weakness and a distinctive skin rash, may occur at any age, but it mostly affects adults in their late 40s to early 60s or children between the ages of 5 and 15. The condition affects more women than men.<sup>7</sup>
- As many as 3 million Americans have **type 1 diabetes**.<sup>8</sup> It is more common in women than men.<sup>6</sup>
- Anyone can get **lupus**, an inflammatory disease that may affect many parts of the body, but 9 out of 10 people who have lupus are women. African-American women are three times more likely to get lupus than white women. Lupus is also more common in Hispanic/Latina, Asian, and Native American women. African Americans and Hispanics/Latinos tend to get lupus at a younger age and have more symptoms, including kidney problems. Lupus also tends to be more severe in these ethnic groups. For example, African Americans with lupus have more problems with seizures and strokes. Hispanic/Latino patients have more heart problems.<sup>9</sup>
- Some 400,000 Americans have **multiple sclerosis (MS)**, which strikes at least two to three times as many women as men. Each week, about 200 people are newly diagnosed with MS, usually between the ages of 20 and 50.<sup>10</sup>
- Most people who develop **polymyalgia rheumatica**, an inflammatory disorder that causes muscle pain and stiffness, are older than 65. It rarely affects people younger than 50. Women are about two times more likely to develop the disorder.<sup>7</sup>
- **Raynaud's disease**, a condition that causes some areas of the body to feel numb and cool in response to cold temperatures or stress, affects women more than men. Although anyone can develop the condition, primary Raynaud's often begins between the ages of 15 and 30. About one-third of people with primary Raynaud's have a first-degree relative—a parent, sibling or child—with the disorder.<sup>7</sup>
- **Scleroderma**, a group of rare, progressive diseases that causes hardening and tightening of the skin and connective tissues, occurs at least four times as often in women as it does in men and usually occurs between the ages of 30 and 50. Systemic scleroderma is more common in African Americans than it is in Americans of European descent, and those African-Americans are more likely to develop severe lung complications.<sup>7</sup>

# FACTS ABOUT DISEASES/CONDITIONS AFFECTING WOMEN IN THE UNITED STATES

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## Autoimmune Diseases (continued)

- The annual direct health care costs for **autoimmune diseases** are estimated to be some \$100 billion.<sup>6</sup>
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## Cancer<sup>11</sup>

- Women have a lifetime risk of a little more than 1 in 3 of developing **cancer**. An estimated 739,940 women were diagnosed with some form of cancer in 2010, and an estimated 270,290 died from cancer that year.
  - An estimated 207,090 women were diagnosed with invasive **breast cancer** last year. It is the most frequently diagnosed cancer in women, excluding cancers of the skin. After continuously increasing from 1994-1999, female breast cancer incidence rates decreased by 2 percent per year from 1999-2006. An estimated 39,840 women died from it in 2010.
  - An estimated 12,200 new cases of invasive **cervical cancer** were diagnosed in 2010. Incidence rates have decreased over the past several decades in both white and African-American women. An estimated 4,210 women died from cervical cancer last year.
  - An estimated 43,470 new cases of **endometrial cancer** (cancer of the uterine corpus) were diagnosed in 2010, and an estimated 7,950 women died from it.
  - Women accounted for 105,770 of the 222,520 new cases of **lung cancer** diagnosed in 2010. While the incidence rate is declining significantly in men (from a high of 102.1 cases per 100,000 in 1984 to 71.3 in 2006), in women the rate is approaching a plateau after a long period of increase. Still, lung cancer accounts for the most cancer-related deaths in both men and women. Since 1987, more women have died each year from lung cancer than from **breast cancer**. Of the estimated 157,300 lung cancer deaths in 2010, 71,080 were in women and 86,220 were in men.
  - An estimated 21,880 new cases of **ovarian cancer** were diagnosed in 2010. It accounts for about 3 percent of all cancers among women and ranks second among **gynecologic cancers**, following **uterine cancer**. An estimated 13,850 women died from ovarian cancer in 2010.
  - The estimated overall costs for **cancer** in 2010 were \$263.8 billion.
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## Eye Disorders

- **Age-related macular degeneration (AMD)** is the leading cause of severe vision loss in adults over age 50. An estimated 1.8 million people have AMD and another 7.3 million are at substantial risk for vision loss from AMD. Caucasians are at higher risk for developing AMD than other races, and women develop AMD at an earlier age than men.<sup>12</sup>
- Nearly 5 million Americans age 50 and older are estimated to have **dry eyes**. Of these, more than 3 million are women and more than 1.5 million are men. Tens of millions more have less severe symptoms. Dry eye is more common after menopause.<sup>13</sup>
- **Glaucoma** is the second leading cause of blindness in the world. More than 4 million Americans have glaucoma, but only half of them know they have it. Some 120,000 are blind from glaucoma, accounting for up to 12 percent of all cases of blindness in this country.<sup>14</sup> Glaucoma is considered an age-related disease. Because women live, on average, several years longer than men do in the United States, many more women than men live long enough to develop glaucoma.<sup>15</sup>
- **Glaucoma** is estimated to cost the U.S. government more than \$1.5 billion annually in Social Security benefits, lost income tax revenues, and health care expenditures.<sup>14</sup>

# FACTS ABOUT DISEASES/CONDITIONS AFFECTING WOMEN IN THE UNITED STATES

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## Gastrointestinal Disorders

- In the United States, 2.1 million people are affected by **irritable bowel syndrome (IBS)**.<sup>1</sup> Women with IBS represent more than 70 percent of IBS sufferers. IBS is responsible for more time lost from school and work than any medical problem—other than the common cold.<sup>16</sup> In 2007, physicians reported that digestive disorders were the primary diagnosis in 2.9 percent of all visits made by women ages 18 and older, accounting for more than 14 million physician visits. IBS was the primary diagnosis in 6.6 percent of visits for digestive disorders.<sup>1</sup>
  - The aggregate cost of **irritable bowel syndrome** in the United States has been estimated at \$30 billion.<sup>16</sup>
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## Heart Disease and Stroke

- Only 13 percent of women view heart disease as a health threat, even though it's the number one killer of women. **Cardiovascular disease (CVD)** kills about one woman per minute. CVD claims more lives than the next four most common causes of death combined. One in three adult females and males in the United States suffers from a form of CVD.<sup>17</sup>
  - **Coronary heart disease** is the leading killer of women over age 25. Sixty-four percent of women who died suddenly of coronary heart disease had no previous symptoms. Heart disease rates in post-menopausal women are two to three times higher than in pre-menopausal women of the same age.<sup>17</sup>
  - **High blood pressure** is a risk factor for a number of conditions, including **heart disease** and **stroke**. From 2005–2008, 16.7 percent of adults were identified with high blood pressure. Among adults ages 65 and older, women are more likely than men to have high blood pressure (41.4 percent versus 32.3 percent, respectively), while men ages 20–44 are more likely than women to have high blood pressure (10.0 versus 3.1 percent, respectively).<sup>1</sup>
  - **High blood pressure** is more prevalent among non-Hispanic Black women than women of other races. From 2005–2008, 21.3 percent of non-Hispanic Black women were found to have high blood pressure, compared to 16.3 percent of non-Hispanic White, 10.6 percent of Mexican-American, and 12.4 percent of other Hispanic women.<sup>1</sup>
  - **Stroke** is the third leading cause of death for American women and a chief cause of serious, long-term disability. Stroke kills more women than men. In 2003, females represented 61 percent of stroke deaths.<sup>17</sup>
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## Kidney/Urologic Disorders

- **Interstitial cystitis (IC)**—also called painful bladder syndrome (PBS)—is nine times more common in women than in men: of the estimated 1.3 million Americans with IC, more than 1 million are women.<sup>18</sup>
- An estimated one-third of people with lupus will develop **lupus nephritis**, a potentially serious symptom of lupus. Lupus nephritis most often develops within the first five years after the symptoms of lupus start, and usually affects people between the ages of 20 and 40. It is estimated that as many as 40 percent of all people with lupus, and as many as two-thirds of all children with lupus, will develop kidney complications that require medical evaluation and treatment.<sup>19</sup>
- About 17 percent of women and 16 percent of men over age 18 have **overactive bladder (OAB)**, and an estimated 12.2 million adults have urge incontinence. One in five adults over age 40 is affected by OAB or recurrent symptoms of urgency and frequency. OAB and urge incontinence occur about twice as frequently in women as in men and become more prevalent with advanced aging. Women with OAB are significantly more likely to suffer from other health disorders, such as **hypertension**, obesity and **arthritis**, than women without OAB. An estimated 17 million community-dwelling adults in the United States have daily urge incontinence and a further 33 million suffer from the overlapping condition OAB.<sup>20</sup>
- **Urinary incontinence (UI)** is one of the most prevalent chronic diseases in the United States and is generally more common among women than men. From 2005–2008, 40.7 percent of women and 12.5 percent of men ages 20 and older reported that they ever had urinary leakage.<sup>1</sup>

# FACTS ABOUT DISEASES/CONDITIONS AFFECTING WOMEN IN THE UNITED STATES

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## Kidney/Urologic Disorders (continued)

- **Urinary tract infections (UTIs)** account for about 8.3 million doctor visits annually. Women are especially prone to UTIs—one woman in five develops a UTI during her lifetime.<sup>18</sup>
- The 1995 societal cost of **UI** for individuals age 65 and older was \$26.3 billion, or \$3,565 per individual age 65 and older with UI. Most of the total cost is associated with direct treatment, such as the cost of diagnostic testing and medication, and nearly half the costs of UI are for medical services paid by Medicare. The cost of **OAB** is \$12.6 billion (in 2000 dollars). The cost of caring for **UI** and **OAB** nursing facility patients is an estimated \$5.3 billion.<sup>20</sup>
- In 2000, \$3.5 billion was spent on the evaluation and treatment of **UTIs**.<sup>18</sup>

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## Lung/Respiratory Disorders<sup>21</sup>

- Females traditionally have consistently higher rates of **asthma** than have males. In 2008, females were about 10.5 percent more likely than males to ever have been diagnosed with asthma. That year, 10.4 million males and 12.9 million females had asthma. The prevalence rate in females (84.6 per 1,000 people) was 19 percent greater than the rate in males (71.1 per 1,000 people) overall.
- Females tend to have consistently higher **asthma attack** prevalence rates than males. In 2008, 7.3 million females had an asthma attack compared to 5.4 million males.
- In 2006, 3,613 people died of **asthma**, and 64 percent of them were women. The female death rate was 44 percent greater than the male death rate. The age-adjusted death rate for asthma in the African-American population (2.7 per 100,000) was three times higher than the rate in the white population (0.9 per 100,000). African-American women had the highest mortality rate due to asthma in 2006 (2.8 per 100,000).
- In 2010, the direct health care costs for **asthma** were \$15.6 billion; indirect costs (lost productivity) added another \$5.1 billion for a total of \$20.7 billion. Prescription drugs represented the largest single direct medical expenditure at \$5.6 billion.
- **Emphysema** and **chronic bronchitis** are the most important conditions that compose **chronic obstructive pulmonary disease (COPD)**, and they frequently coexist. In 2008, 12.1 million U.S. adults ages 18 and older were estimated to have COPD. Women were more than twice as likely to be diagnosed with **chronic bronchitis** as men. In 2008, 3.1 million men were diagnosed with chronic bronchitis compared to 6.7 million women. Women have had lower **emphysema** prevalence rates than men for every year since 1983. However, in 2008 the rates converged and switched, although the difference between them was not statistically significant. In 2008, almost 1.8 million men had emphysema, compared to more than 2.0 million women. From 1997 to 2008, the prevalence rate of emphysema among men decreased by 19.3 percent, while the rate among women increased by 32.1 percent.
- In 2006, 120,970 people died of **COPD**, compared to 127,049 in 2005; 52.1 percent of those deaths were in women. That was the seventh consecutive year in which the number of deaths due to COPD was higher among women than men.
- The national projected annual cost for **COPD** in 2010 was \$49.9 billion.
- The number of deaths due to **pneumonia** and **influenza** has been higher among females since the mid-1980s. However, females have age-adjusted death rates close to 30 percent lower than those in men because the U.S. female population is larger than the male population. In 2006, the age-adjusted death rates for females and males were 15.5 and 21.2 per 100,000, respectively.

# FACTS ABOUT DISEASES/CONDITIONS AFFECTING WOMEN IN THE UNITED STATES

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## Lung/Respiratory Disorders<sup>21</sup> (continued)

- An estimated 589,000 hospital discharges in males and 643,000 discharges in females were attributed to **pneumonia** in 2006. That year, an estimated 12,000 discharges in males and 25,000 discharges in females were attributed to **influenza**.
  - Together, **pneumonia** and **influenza** cost the U.S. economy \$40.2 billion in 2005.
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## Neurologic Disorders

- **Alzheimer's disease** is the most common type of **dementia**, accounting for an estimated 60 percent to 80 percent of cases. More women than men have Alzheimer's disease and other dementias. Almost two-thirds of all Americans living with Alzheimer's are women. Of the 5.2 million people over age 65 with Alzheimer's in the United States, 3.4 million are women and 1.8 million are men. An estimated 16 percent of women ages 71 and older have Alzheimer's disease or other dementia compared with 11 percent of men. The fact that more older women than men have Alzheimer's disease or other dementia is primarily due to women living longer on average than men.<sup>22</sup>
  - Of the estimated 28 million **migraine** sufferers, 75 percent, or about 21 million, are women. More than 157 million workdays are lost each year due to migraines. Missed work or reduced productivity due to migraines costs the economy \$13 billion annually.<sup>23</sup>
  - For people with **Alzheimer's disease** and other **dementias**, aggregate payments for health care, long-term care, and hospice are projected to increase from \$183 billion in 2011 to \$1.1 trillion in 2050 (in 2011 dollars). Medicare and Medicaid cover about 70 percent of the costs of care.<sup>22</sup>
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## Obstetric/Gynecologic Conditions

- An estimated 21.2 million women ages 14–49 have **bacterial vaginosis (BV)**, the most common cause of vaginal symptoms in women. The BV prevalence rate for African-American women is 51 percent, for Mexican-American women 32 percent, and for white women 23 percent.<sup>24</sup>
  - Some 62 million American women are in their childbearing years (15–44), and 62 percent of them are using a **contraceptive** method. Almost one-third (31 percent) of those women do not need a contraceptive because they are infertile; pregnant, postpartum, or trying to become pregnant; have never had intercourse; or are not sexually active. Among the 43 million fertile, sexually active women who do not want to become pregnant, 89 percent are practicing contraception. For women younger than age 30, birth control pills are the leading method. Among women ages 30 and older, more rely on sterilization.<sup>25</sup>
  - Approximately 20 million Americans are currently infected with **human papillomavirus (HPV)**. Another 6 million people become newly infected each year. HPV is so common that at least 50 percent of sexually active men and women get it at some point in their lives. Some types of HPV cause **genital warts**, which about 1 percent of sexually active U.S. adults have at any one time. Other types of HPV cause **cervical cancer**, which strikes about 12,000 women annually in this country.<sup>24</sup>
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## Psychiatric Disorders

- The U.S. Congress Office of Technology Assessment estimates that as many as 6.8 million people in the United States have **dementia**, and at least 1.8 million of those are severely affected. **Vascular dementia** is the second most common cause of dementia, after **Alzheimer's disease**. It accounts for up to 20 percent of all dementias and is caused by brain damage from cerebrovascular or cardiovascular problems—usually strokes. The incidence of vascular dementia increases with advancing age and is similar in men and women.<sup>26</sup> A recent study found that women over age 90 are significantly more likely to have **dementia** than men of the same age. It found that the likelihood of having dementia doubled every five years in women after reaching 90, but not in men.<sup>27</sup>



# FACTS ABOUT DISEASES/CONDITIONS AFFECTING WOMEN IN THE UNITED STATES

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## Psychiatric Disorders (continued)

- One in four women will experience severe **depression** at some point in life. Depression affects twice as many women as men, regardless of racial and ethnic background or income, and it is the number one cause of disability in women. In general, married women experience depression more than single women do, and depression is common among young mothers who stay at home full-time with small children. Depression can put women at risk of suicide. While more men than women die from suicide, women attempt suicide about twice as often as men do. Only about one-fifth of all women who suffer from depression seek treatment.<sup>28</sup>
- **Generalized anxiety disorder (GAD)** affects about 6.8 million adult Americans and about twice as many women as men. The disorder comes on gradually and can begin across the life cycle, though the risk is highest between childhood and middle age.<sup>29</sup>
- Approximately 1 in 23 people suffer from **phobias** (social, agoraphobic, and specific). That's nearly 4.25 percent of the population. Some 5.2 million Americans (ages 18 to 54) have social phobia. Approximately 3.2 million Americans have agoraphobia. Almost 6.2 million U.S. citizens have some sort of specific phobia. Roughly twice as many women as men suffer from specific phobia, while about equal numbers of women and men have social phobia.<sup>30</sup>
- An estimated 5 million people in the United States are afflicted with **post-traumatic stress disorder (PTSD)** every year. About 8 percent of men who experienced traumatic events in their lives may suffer from PTSD, while 20 percent of women exposed to traumatic events are likely to be afflicted with PTSD.<sup>31</sup>

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## Other

- More than 3 million people in the United States have **anemia**. Women and people with chronic diseases are at greatest risk.<sup>9</sup> Some 20 percent of pregnant women in this country have anemia, and 12 percent of women ages 12-49 are iron deficient.<sup>32</sup>
- **Chronic fatigue syndrome (CFS)** is estimated to affect between 1 million and 4 million people in the United States; however, an estimated 80 percent of all CFS patients have not yet been diagnosed. Only about half of CFS patients have sought medical attention and fewer than one in five has been diagnosed and treated. CFS occurs most frequently in women ages 40-60, but it affects all races, sexes, and age groups, and can be as disabling as **multiple sclerosis** and **chronic obstructive pulmonary disease**. One-fourth of those affected by CFS are either unemployed or on disability assistance.<sup>24</sup>
- Up to 24 million people of all ages and genders suffer from an **eating disorder (anorexia, bulimia, and binge-eating disorder)** in the United States. Women are much more likely than men to develop an eating disorder. Only an estimated 5 percent to 15 percent of people with anorexia or bulimia are male. Of those who have eating disorders, 95 percent are between the ages of 12 and 25.<sup>33</sup>
- **Anorexia** is the third most common chronic illness among adolescents. An estimated 0.5 percent to 3.7 percent of women suffer from anorexia nervosa in their lifetime. Research suggests that about 1 percent of female adolescents have anorexia. About 50 percent of people who have had anorexia develop **bulimia** or bulimic patterns. Twenty percent of people suffering from anorexia will prematurely die from complications related to their eating disorder, including suicide and heart problems. The mortality rate associated with anorexia nervosa is 12 times higher than the death rate associated with all causes of death for females 15-24 years old. The crude mortality rate for anorexia nervosa is 4 percent.<sup>33</sup>
- Severe **sepsis** is reported in 2.26 cases per 100 hospital discharges and one in five admissions to the intensive care unit (ICU). Of the more than 750,000 severe sepsis cases each year in the United States, an estimated 215,000 (28.6%) patients die. Mortality associated with severe sepsis has been reported as high as 50 percent.<sup>34</sup> Septicemia, which is a state of sepsis, killed 18,989 females and 15,839 males in 2007.<sup>24</sup> Severe sepsis accounts for an estimated 40 percent of all ICU expenditures, totaling \$16.7 billion.<sup>34</sup>

# FACTS ABOUT DISEASES/CONDITIONS AFFECTING WOMEN IN THE UNITED STATES

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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.

		Clinical Trials			FDA	Phase IV
		Phase I	Phase II	Phase III		
Years	6.5	1.5	2	3.5	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 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 usually 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 and determine the early side effect profile.

**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 25 new therapeutics approved by the FDA in 2009 was 13.3 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 \$67.4 billion in research and development in 2010.

# TRACKING THE BIOPHARMACEUTICAL RESEARCH PIPELINE

Today, more than 3,000 new medicines are in development in the United States. Many of these potential new medicines will fail in clinical trials, but some may represent tomorrow's new treatments. Bringing each new medicine to patients will require, on average, 10 to 15 years of testing and review.

PhRMA publishes several reports that track the biopharmaceutical research pipeline for many diseases, including the leading causes of death among Americans—heart disease, cancer, and stroke. The reports include medicines currently in clinical trials or at the U.S. Food and Drug Administration (FDA) for review. Below is a summary of our most popular reports.

- **Cancer**—There are few things that cause patients more fear and uncertainty as a cancer diagnosis. Yet today—because of a steady stream of new and improved medicines and treatments—cancer can increasingly be managed and even beaten. *The 2011 report found 887 medicines in the pipeline.*
- **Heart Disease and Stroke**—Keeping up the momentum of drug discovery that has helped cut deaths from heart disease and stroke in half in the past three decades, biopharmaceutical companies are working on new medicines for these diseases. *The 2011 report found 299 medicines in the pipeline.*
- **Diabetes**—Approximately 4,110 people are diagnosed with diabetes every day. To help fight this disease, pharmaceutical and biotechnology researchers are working on new medicines to treat it and related conditions. *The 2010 report found 235 medicines in the pipeline.*
- **Mental Illnesses**—Pharmaceutical and biotechnology researchers are testing many new medicines to help the more than 450 million people worldwide who suffer from some form of mental illness. *The 2010 report found 313 medicines in the pipeline.*
- **Biotechnology**—Millions of people have already benefited from medicines and vaccines developed through biotechnology, and a new report offers hope that many more will benefit in the future. *The 2008 report found 633 medicines in the pipeline.*
- **Children**—Biopharmaceutical researchers are testing medicines to meet the special needs of children. These medicines offer hope that the significant improvements achieved in children's health over the past few decades will continue and even accelerate. *The 2010 report found 234 medicines in the pipeline.*
- **Infectious Diseases**—Throughout history, infectious diseases have taken a devastating toll on the lives and well-being of people around the world. Today, vaccines and antibiotics have proven to be effective treatments in many cases, but infectious diseases still pose a very serious threat to patients. Infectious diseases may never be eradicated. But, new knowledge, new technologies, and a huge commitment of resources by America's biopharmaceutical research companies and the government can help meet the continuing—and ever-changing—threat from infectious diseases. *The 2010 report found 395 medicines in the pipeline.*



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