

# Neurologic Disorders

PRESENTED BY AMERICA'S PHARMACEUTICAL COMPANIES

## Pharmaceutical Companies Developing 241 Medicines for Neurologic Disorders

America's research-based pharmaceutical and biotechnology companies are developing 241 new medicines to treat debilitating neurological disorders such as Alzheimer's, epilepsy, multiple sclerosis, Parkinson's, and stroke. Combined, the disorders targeted by this research inflict great pain and suffering on patients and their families and every year cost the U.S. economy hundreds of billions of dollars in care, lost work days, and reduced productivity. The economic cost of Alzheimer's alone, for example, totals at least \$100 billion annually.

The medicines in development (either in human clinical trials or at the Food and Drug Administration awaiting approval) include:

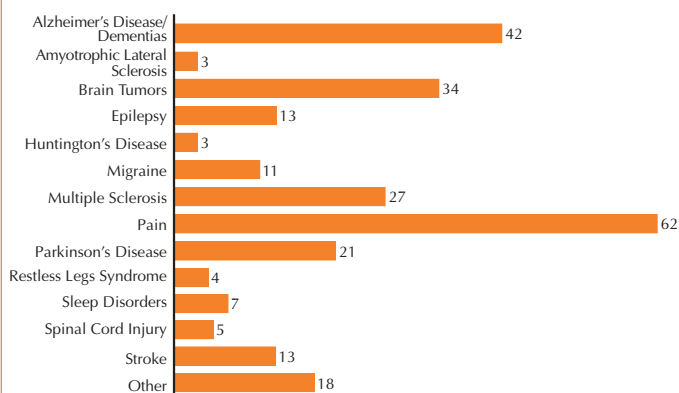
- 62 medicines for pain, the most common reason Americans seek medical care, with 57 percent of U.S. adults having experienced chronic or recurrent pain in the last year.
- 34 medicines for brain tumors, with an estimated 359,000 Americans having a primary brain tumor.
- 42 medicines for Alzheimer's disease, which afflicts about 4.5 million Americans, including 1 in 10 people over 65 and nearly half of those over 85.
- 21 medicines for Parkinson's disease, which affects as many as 1.5 million Americans.
- 13 medicines for stroke, the third leading cause of death after heart disease and cancer.
- 11 medicines for migraine, a condition that affects about 28 million people or 13 percent of the U.S. population.
- 27 medicines for multiple sclerosis, which afflicts some 400,000 Americans.
- 13 medicines for epilepsy; more than 2 million Americans have experienced an unprovoked seizure or have been diagnosed with the disease.

Other medicines in development target brain injuries, Huntington's disease, spinal cord injury, myasthenia gravis, juvenile cerebral palsy, and restless legs syndrome.

The many promising new medicines in development include:

- A medicine that uses normal human cells to enhance brain levels of dopamine, the neurotransmitter deficient in Parkinson's patients.

### 2006 MEDICINES IN DEVELOPMENT FOR NEUROLOGIC DISORDERS\*



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

- A medicine for glioblastoma (brain cancer) that singles out and latches onto the receptors on the surface of the malignant cells—but not the healthy cells—and destroys them.
- A medicine for Alzheimer's that both inhibits plaque formation and blocks the degradation of the neurotransmitter acetylcholine.

The new medicines now in the research pipeline will add to the substantial progress made in the last five years by pharmaceutical and biotechnology companies in developing new and more effective neurologic treatments. They are giving patients and health-care providers new hope that more effective treatments and even possible cures may soon be available. This strong commitment to research—building on the past, continuing in the present, and heading into the future—is a product of the determination of the men and women working for America's research-based pharmaceutical companies to develop new medicines to help patients live longer, healthier, and more productive lives.

Billy Tauzin  
President and CEO  
PhRMA

# Medicines in Development for Neurologic Disorders

## ALZHEIMER'S DISEASE/DEMENTIAS

Product Name	Sponsor	Indication	Development Status*
189254 (histamine H3 antagonist)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	dementia	Phase I (888) 825-5249
742457 (5HT6 antagonist)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	dementia	Phase II (888) 825-5249
AAB-001	Wyeth Pharmaceuticals Collegeville, PA Elan Pharmaceuticals San Diego, CA	Alzheimer's disease (passive immunotherapy)	Phase II (610) 902-1200
ABT-089	Abbott Laboratories Abbott Park, IL	Alzheimer's disease	Phase II (847) 937-6100
ABT-239	Abbott Laboratories Abbott Park, IL	cognition	Phase I (847) 937-6100
ABT-834	Abbott Laboratories Abbott Park, IL	cognition	Phase I (847) 937-6100
<b>Agilect</b> <sup>®</sup> rasagiline mesylate	Teva Pharmaceuticals North America North Wales, PA	Alzheimer's disease (see also Parkinson's)	Phase II (215) 591-3000
AL-108	Allon Therapeutics Vancouver, British Columbia	Alzheimer's disease	Phase I (604) 736-0634
AL-208	Allon Therapeutics Vancouver, British Columbia	mild cognitive impairment	Phase I (604) 736-0634
<b>Alzhemed</b> <sup>™</sup>	Neurochem Laval, Quebec	mild to moderate Alzheimer's disease	Phase III (866) 680-4456
<b>Ampalex</b> <sup>®</sup> (CX516)	Cortex Pharmaceuticals Irvine, CA	mild cognitive impairment (see also other)	Phase II completed (949) 727-3157
<b>Aricept</b> <sup>®</sup> donepezil hydrochloride	Eisai Ridgefield Park, NJ Pfizer New York, NY	vascular dementia  ----- severe Alzheimer's disease, mild cognitive impairment (see also migraine)	application submitted (888) 274-2378  Phase III (888) 274-2378
<b>Avandia</b> <sup>®</sup> rosiglitazone maleate	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	Alzheimer's disease	Phase II (888) 825-5249
C 9136	Merck Whitehouse Station, NJ	Alzheimer's disease	Phase II (908) 423-1000
CERE-110 (growth factor gene therapy)	Ceregene San Diego, CA	Alzheimer's disease	Phase I (858) 458-8800

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

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Product Name	Sponsor	Indication	Development Status*
CX717	Cortex Pharmaceuticals <i>Irvine, CA</i>	Alzheimer's disease	Phase II (949) 727-3157
<b>Exelon® TDS</b>	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	Alzheimer's disease	in clinical trials (888) NOW-NOVA
FK962	Astellas Pharma US <i>Deerfield, IL</i>	Alzheimer's disease	Phase II (800) 727-7003
<b>Flurizan™</b> MPC-7869	Myriad Genetics <i>Salt Lake City, UT</i>	Alzheimer's disease	Phase III (801) 584-3600
IPL455,903 (HT-0712)	Inflazyme Pharmaceuticals <i>Vancouver, British Columbia</i> Helicon Therapeutics <i>Farmingdale, NY</i>	age-associated memory impairment	Phase II (604) 279-8511 (631) 370-8818
ladostigil tartrate	Teva Pharmaceuticals North America <i>North Wales, PA</i>	Alzheimer's disease	Phase II (215) 591-3000
lecozotan	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	Alzheimer's disease	Phase II (610) 902-1200
LY450139	Eli Lilly <i>Indianapolis, IN</i>	Alzheimer's disease	Phase II (317) 276-2000
MEM-1003	Memory Pharmaceuticals <i>Montvale, NJ</i>	Alzheimer's disease, mild cognitive impairment, vascular dementia	Phase II (201) 802-7100
MEM-1414	Memory Pharmaceuticals <i>Montvale, NJ</i>	Alzheimer's disease	Phase I (201) 802-7100
MEM-3454	Memory Pharmaceuticals <i>Montvale, NJ</i>	Alzheimer's disease	Phase I completed (201) 802-7100
<b>Memryte™</b> leuprolide acetate	DURECT <i>Cupertino, CA</i> Voyager Pharmaceuticals <i>Raleigh, NC</i>	Alzheimer's disease	Phase III (408) 777-1417
MX-4509	Migenix <i>San Diego, CA</i>	Alzheimer's disease	Phase I completed (858) 793-7800
<b>Namenda</b> memantine HCl	Forest Laboratories <i>New York, NY</i>	mild Alzheimer's disease	application submitted (800) 947-5227
neramexane	Forest Laboratories <i>New York, NY</i>	moderate to severe Alzheimer's disease (see also pain)	Phase III (800) 947-5227
NGX267	TorreyPines Therapeutics <i>La Jolla, CA</i>	Alzheimer's disease	Phase I (858) 623-5665
NS 2330	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	Alzheimer's disease (see also Parkinson's)	Phase II (203) 798-4700
phenserine tartrate	Axonix <i>New York, NY</i>	Alzheimer's disease	Phase III (212) 688-4770
PRX-03140	Predix Pharmaceuticals <i>Lexington, MA</i>	Alzheimer's disease	Phase I (781) 372-3260

## ALZHEIMER'S DISEASE/DEMENTIAS

Product Name	Sponsor	Indication	Development Status*
Risperdal®	Johnson & Johnson Pharmaceutical Research & Development Raritan, NJ	psychosis in Alzheimer's dementia	application submitted (800) 817-5286
SGS742	Saegis Pharmaceuticals Half Moon Bay, CA	Alzheimer's disease, mild cognitive impairment	Phase II (650) 560-1210
SR 57667	sanofi-aventis Bridgewater, NJ	Alzheimer's disease (see also Parkinson's)	Phase II (800) 633-1610
SR 57746 xaliproden	sanofi-aventis Bridgewater, NJ	Alzheimer's disease (see also other)	Phase III (800) 633-1610
T-817MA	Toyama Chemical Tokyo, Japan	Alzheimer's disease	Phase I
Tanakan®	Ipsen Milford, MA	mild cognitive impairment related to age	Phase III (508) 478-8900
TC-1734	AstraZeneca Wilmington, DE Targacept Winston-Salem, NC	cognitive disorders	Phase II (302) 886-3000 (336) 480-2100
TTP488	TransTech Pharma High Point, NC	Alzheimer's disease	Phase II (336) 841-0300

## AMYOTROPHIC LATERAL SCLEROSIS (ALS)

Product Name	Sponsor	Indication	Development Status
AEOL 10150	Aeolus Pharmaceuticals Laguna Niguel, CA	amyotrophic lateral sclerosis (ALS)	Phase I completed (949) 481-9825
arimoclomol	Cytrx Los Angeles, CA	ALS	Phase II (310) 826-5648
Myogane™ PYM50018	Phytopharm Cambridgeshire, United Kingdom	ALS	Phase I <a href="http://www.phytopharm.com">www.phytopharm.com</a>

## BRAIN TUMORS

Product Name	Sponsor	Indication	Development Status
131 I-TM-601 (Orphan Drug)	TransMolecular Cambridge, MA	recurrent high-grade glioma	Phase II (617) 995-3050
BAY 43-9006	National Cancer Institute Bethesda, MD Bayer Pharmaceuticals West Haven, CT	glioblastoma multiforme	Phase I N C I T R I A L (800) 4-CANCER
CAI	National Cancer Institute Bethesda, MD	glioblastoma multiforme	Phase II N C I T R I A L (800) 4-CANCER

## BRAIN TUMORS

Product Name	Sponsor	Indication	Development Status
CCI-779 (rapamycin analog)	National Cancer Institute <i>Bethesda, MD</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	low-grade astrocytoma	Phase II N C I T R I A L (800) 4-CANCER
		glioblastoma multiforme	Phase I/II N C I T R I A L (800) 4-CANCER
COL-3	National Cancer Institute <i>Bethesda, MD</i> CollaGenex Pharmaceuticals <i>Newtown, PA</i>	glioblastoma multiforme	Phase I/II N C I T R I A L (800) 4-CANCER
EF-5	National Cancer Institute <i>Bethesda, MD</i>	low-grade astrocytoma	in clinical trials N C I T R I A L (800) 4-CANCER
<b>Efaproxyn™</b> efaproxiral	Allos Therapeutics <i>Westminster, CO</i>	brain metastases from breast cancer	Phase III (303) 426-6262
		glioma	Phase II (303) 426-6262
<b>Eloxatin™</b> oxaliplatin	National Cancer Institute <i>Bethesda, MD</i> sanofi-aventis <i>Bridgewater, NJ</i>	medulloblastoma	Phase II N C I T R I A L (800) 4-CANCER
		glioblastoma multiforme	Phase I/II N C I T R I A L (800) 4-CANCER
EMD-121974 (cilengitide)	National Cancer Institute <i>Bethesda, MD</i> Merck KgaA <i>Darmstadt, Germany</i>	glioblastoma multiforme	Phase I/II N C I T R I A L (800) 4-CANCER
		central nervous system (CNS) primary tumor	Phase I N C I T R I A L (800) 4-CANCER
epothilone-B (BMS 247550)	National Cancer Institute <i>Bethesda, MD</i> Bristol-Myers Squibb <i>Princeton, NJ</i>	anaplastic astrocytoma	Phase I/II N C I T R I A L (800) 4-CANCER
F-18, EF-5	National Cancer Institute <i>Bethesda, MD</i>	CNS primary tumor	Phase I N C I T R I A L (800) 4-CANCER
F-18, FK228	National Cancer Institute <i>Bethesda, MD</i> Gloucester Pharmaceuticals <i>Cambridge, MA</i>	glioblastoma multiforme	Phase I/II N C I T R I A L (800) 4-CANCER
fenretinide (4-HPR)	National Cancer Institute <i>Bethesda, MD</i>	neuroblastoma	Phase II N C I T R I A L (800) 4-CANCER
<b>Gleevec</b> imatinib mesylate (STI571)	National Cancer Institute <i>Bethesda, MD</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	anaplastic oligodendroglioma, diffuse brain stem glioma, meningioma	Phase II N C I T R I A L (800) 4-CANCER

## BRAIN TUMORS

Product Name	Sponsor	Indication	Development Status
<b>Hycamtin™</b> topotecan	National Cancer Institute <i>Bethesda, MD</i> GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	meningioma	Phase II N C I T R I A L (800) 4-CANCER
IL 13-PE38QQR (cintredekin besudotox) <b>(Orphan Drug)</b>	Neopharm <i>Lake Forest, IL</i>	glioblastoma multiforme (first recurrent) ----- glioblastoma multiforme (initial diagnosis)	Phase III (847) 295-8678  Phase I (847) 295-8678
INO-1001	Inotek Pharmaceuticals <i>Beverly, MA</i>	glioma	Phase I (978) 232-9660
interleukin-12	National Cancer Institute <i>Bethesda, MD</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	neuroblastoma	Phase I N C I T R I A L (800) 4-CANCER
<b>Iressa®</b> gefitinib	National Cancer Institute <i>Bethesda, MD</i> AstraZeneca <i>Wilmington, DE</i>	diffuse brainstem glioma, glioblastoma multiforme	Phase I/II N C I T R I A L (800) 4-CANCER
irofulven (MGI-114)	National Cancer Institute <i>Bethesda, MD</i> MGI Pharma <i>Bloomington, MN</i>	glioblastoma multiforme	Phase I/II N C I T R I A L (800) 4-CANCER
lapatinib	National Cancer Institute <i>Bethesda, MD</i> GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	glioblastoma multiforme ----- CNS primary tumor	Phase II N C I T R I A L (800) 4-CANCER  Phase I/II N C I T R I A L (800) 4-CANCER
MoAb 14.18, chimeric (CH 14.18)	National Cancer Institute <i>Bethesda, MD</i>	neuroblastoma	Phase III N C I T R I A L (800) 4-CANCER
NBI-3001 (IL-4 fusion toxin)	Neurocrine Biosciences <i>San Diego, CA</i>	glioblastoma	Phase I/II (858) 658-7600
O-6-benzylguanine	National Cancer Institute <i>Bethesda, MD</i> Keryx BioPharmaceuticals <i>Stamford, CT</i>	glioblastoma multiforme ----- CNS primary tumor	Phase III N C I T R I A L (800) 4-CANCER  Phase I N C I T R I A L (800) 4-CANCER
pyrazoloacridine	National Cancer Institute <i>Bethesda, MD</i> Pfizer <i>New York, NY</i>	low-grade astrocytoma ----- neuroblastoma	Phase I/II N C I T R I A L (800) 4-CANCER  Phase I N C I T R I A L (800) 4-CANCER

## BRAIN TUMORS

Product Name	Sponsor	Indication	Development Status
<b>Revlimid</b> lenalidomide	National Cancer Institute <i>Bethesda, MD</i> Celgene <i>Summit, NJ</i>	CNS primary tumor	Phase I N C I T R I A L (800) 4-CANCER
<b>Tarceva™</b> erlotinib	National Cancer Institute <i>Bethesda, MD</i> OSI Pharmaceuticals <i>Melville, NY</i>	glioblastoma multiforme	Phase I/II N C I T R I A L (800) 4-CANCER
<b>Temodar</b>	Schering-Plough <i>Kenilworth, NJ</i>	brain metastases	Phase II (908) 298-4000
<b>Trisenox™</b> arsenic trioxide	National Cancer Institute <i>Bethesda, MD</i> Cell Therapeutics <i>Seattle, WA</i>	glioblastoma multiforme	Phase I N C I T R I A L (800) 4-CANCER
<b>Velcade</b> bortezomib	National Cancer Institute <i>Bethesda, MD</i> Millennium Pharmaceuticals <i>Cambridge, MA</i>	glioblastoma multiforme	Phase I N C I T R I A L (800) 4-CANCER
<b>Xerecept®</b> corticotropin acetate	Neurobiological Technologies <i>Emeryville, CA</i>	peritumoral brain edema	Phase III (510) 595-6000
<b>Xcytrin</b> motexafin gadolinium	Pharmacyclics <i>Sunnyvale, CA</i>	lung cancer brain metastases (in combination with radiation)	Phase III (408) 774-0330
		brain metastases radiosurgery (in combination with radiation)	Phase II (408) 774-0330
		glioma (in combination with chemotherapy)	Phase I (408) 774-0330
XL 119 becatecarin, rebeccamycin analog	National Cancer Institute <i>Bethesda, MD</i> Exelixis <i>South San Francisco, CA</i>	neuroblastoma	Phase II N C I T R I A L (800) 4-CANCER
<b>Zarnestra</b> tipifarnib	National Cancer Institute <i>Bethesda, MD</i> Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	glioblastoma multiforme, neurofibromatosis	Phase II N C I T R I A L (800) 4-CANCER
		diffuse brain stem glioma	Phase I/II N C I T R I A L (800) 4-CANCER

## EPILEPSY

Product Name	Sponsor	Indication	Development Status
406725 (gap junction blocker)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	epilepsy (see also migraine, pain)	Phase I (888) 825-5249
<b>Ampanel</b> talampanel	IVAX <i>Miami, FL</i>	epilepsy	Phase II (305) 575-6000

## EPILEPSY

Product Name	Sponsor	Indication	Development Status
E2007	Eisai <i>Ridgefield Park, NJ</i>	epilepsy (see also migraine, multiple sclerosis, Parkinson's)	Phase II (888) 274-2378
isovaleramide (NPS 1776)	NPS Pharmaceuticals <i>Salt Lake City, UT</i>	epilepsy	Phase I (801) 583-4939
lacosamide	Schwarz Pharma <i>Milwaukee, WI</i>	epilepsy (see also pain)	Phase III (800) 558-5114
<b>Lamictal® XR</b> lamotrigine (once daily)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	epilepsy	Phase III (888) 825-5249
lorazepam (nasal therapy)	Intranasal Therapeutics <i>Lexington, KY</i>	seizures	Phase I (859) 252-5080
PW4110	Penwest Pharmaceuticals <i>Danbury, CT</i>	epilepsy	Phase I (203) 796-3700
retigabine	Valeant Pharmaceuticals <i>Costa Mesa, CA</i>	partial-onset seizures in patients with epilepsy	Phase II (800) 548-5100
rufinamide	Eisai <i>Ridgefield Park, NJ</i>	epilepsy	Phase III (888) 274-2378
RWJ-333369 (YKP 509)	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> SK Biopharmaceutical <i>Fairfield, NJ</i>	epilepsy	Phase II (800) 817-5286
<b>Sabril</b> vigabatrin (Orphan Drug)	Ovation Pharmaceuticals <i>Deerfield, IL</i>	adult complex partial seizures ----- infantile spasms	application submitted (800) 455-1141  Phase III (800) 455-1141
YKP 509	SK Bio-Pharmaceuticals <i>Seoul, South Korea</i>	epilepsy	Phase II

## HUNTINGTON'S DISEASE

Product Name	Sponsor	Indication	Development Status
ACR16 (Orphan Drug)	Carlsson Research <i>Göteborg, Sweden</i>	Huntington's disease	Phase II <a href="http://www.carlssonresearch.com">www.carlssonresearch.com</a>
minocycline	Huntington Study Group <i>Rochester, NY</i>	Huntington's disease	Phase II/III
<b>Miraxion</b>	Amarin <i>London, England</i> Huntington Study Group <i>Rochester, NY</i>	Huntington's disease	Phase III <a href="http://www.amarincorp.com">www.amarincorp.com</a>

## MIGRAINE

Product Name	Sponsor	Indication	Development Status
274150 (selective iNOS inhibitor)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	migraine	Phase II (888) 825-5249
406381 (dual-acting COX-2 inhibitor)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	migraine (see also pain)	Phase III (888) 825-5249
406725 (gap junction blocker)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	migraine (see also epilepsy, pain)	Phase I (888) 825-5249
705498 (vanilloid 1 antagonist)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	acute migraine	Phase II (888) 825-5249
<b>Aricept</b> <sup>®</sup> donepezil hydrochloride	Eisai Ridgefield Park, NJ	migraine (see also Alzheimer's/dementias)	Phase II (888) 274-2378
butorphanol (nasal therapy)	Intranasal Therapeutics Lexington, KY	migraine pain	Phase III (859) 252-5080
E2007	Eisai Ridgefield Park, NJ	migraine prophylaxis (see also epilepsy, multiple sclerosis, Parkinson's)	Phase II (888) 274-2378
<b>Frova</b> <sup>™</sup> frovatriptan	Endo Pharmaceuticals Chadds Ford, PA	prevention of menstrually-associated migraine	Phase III (610) 558-9800
intraject sumatriptan	Aradigm Hayward, CA	migraine	Phase III (510) 265-9000
NGX424-SC	TorreyPines Therapeutics La Jolla, CA	migraine	Phase I (858) 623-5665
<b>Trexima</b> <sup>™</sup> sumatriptan succinate/ naproxen sodium (fixed-dose combination)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC POZEN Chapel Hill, NC	migraine (acute treatment)	application submitted (888) 825-5249 (919) 913-1030

## MULTIPLE SCLEROSIS

Product Name	Sponsor	Indication	Development Status
683699 (dual alpha4 integrin antagonist)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	multiple sclerosis	Phase II (888) 825-5249
ATL1102 (ISIS 107248)	Antisense Therapeutics Melbourne, Australia Isis Pharmaceuticals Carlsbad, CA	multiple sclerosis	Phase II (760) 931-9200
BG-12/oral fumarate	Biogen Idec Cambridge, MA	multiple sclerosis (relapsing forms)	Phase II (617) 679-2000

## MULTIPLE SCLEROSIS

Product Name	Sponsor	Indication	Development Status
BHT-3009	Bayhill Therapeutics <i>Palo Alto, CA</i>	multiple sclerosis	Phase I/II (650) 320-2800
C 6448	Merck <i>Whitehouse Station, NJ</i>	multiple sclerosis	Phase II (908) 423-1000
<b>Campath</b> <sup>®</sup> alemtuzumab	Genzyme <i>Cambridge, MA</i>	multiple sclerosis	Phase II (800) 745-4447
CCR2	ChemoCentryx <i>Mountain View, CA</i>	multiple sclerosis	Phase I (650) 210-2900
CNTO 1275	Centocor <i>Horsham, PA</i>	multiple sclerosis	Phase II (610) 651-6000
<b>Copaxone</b> <sup>®</sup> glatiramer acetate (oral)	Teva Pharmaceuticals North America <i>North Wales, PA</i>	relapsing-remitting multiple sclerosis	Phase II (215) 591-3000
daclizumab	Biogen Idec <i>Cambridge, MA</i>	multiple sclerosis (relapsing forms)	Phase II (617) 679-2000
E2007	Eisai <i>Ridgefield Park, NJ</i>	multiple sclerosis (see also epilepsy, migraine, Parkinson's)	Phase II (888) 274-2378
fampridine-SR	Acorda Therapeutics <i>Hawthorne, NY</i>	multiple sclerosis (see also spinal cord injury)	Phase III (914) 347-4300
HMR 1726 teriflunomide	sanofi-aventis <i>Bridgewater, NJ</i>	multiple sclerosis	Phase III (800) 633-1610
JNK inhibitor	Serono <i>Rockland, MA</i>	multiple sclerosis	Phase I (800) 283-8088
laquinimod	Teva Pharmaceuticals North America <i>North Wales, PA</i>	relapsing-remitting multiple sclerosis	Phase II (215) 591-3000
MLN 1202	Millennium Pharmaceuticals <i>Cambridge, MA</i>	multiple sclerosis	Phase II (800) 390-5663
MLN 3897	Millennium Pharmaceuticals <i>Cambridge, MA</i>	multiple sclerosis	Phase I (800) 390-5663
MMP-12 inhibitor	Serono <i>Rockland, MA</i>	multiple sclerosis	Phase I (800) 283-8088
MN-166	MediciNova <i>San Diego, CA</i>	multiple sclerosis	Phase II (858) 373-1500
NBI-5788	Neurocrine Biosciences <i>San Diego, CA</i>	multiple sclerosis	Phase II (858) 617-7600
<b>NeuroVax</b> <sup>™</sup>	Immune Response <i>Carlsbad, CA</i>	multiple sclerosis	Phase II (760) 431-7080
oral cladribine	Serono <i>Rockland, MA</i>	multiple sclerosis	Phase III (800) 283-8088
RG2077 (CTLA4-Ig)	Repligen <i>Waltham, MA</i>	multiple sclerosis	Phase I (781) 250-0111

## MULTIPLE SCLEROSIS

Product Name	Sponsor	Indication	Development Status
<b>Rituxan</b> <sup>®</sup> rituximab	Biogen Idec Cambridge, MA Genentech South San Francisco, CA	primary progressive multiple sclerosis (see also other)	Phase II/III (617) 679-2000 (650) 225-1000
		relapsing-remitting multiple sclerosis	Phase II (617) 679-2000 (650) 225-1000
<b>Tauferon</b> <sup>™</sup> interferon-tau	Pepgen Alameda, CA	multiple sclerosis	Phase II (510) 473-0010
<b>Tovaxin</b> <sup>™</sup> autologous T-cell therapy	PharmaFrontiers The Woodlands, TX	multiple sclerosis	Phase I/II (281) 272-9331
TV-5010	Teva Pharmaceuticals North America North Wales, PA	relapsing-remitting multiple sclerosis	Phase II (215) 591-3000

## PAIN

Product Name	Sponsor	Indication	Development Status
406381 (dual-acting COX-2 inhibitor)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	acute and chronic pain (see also migraine)	Phase III (888) 825-5249
406725 (gap junction blocker)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	neuropathic pain (see also epilepsy, migraine)	Phase I (888) 825-5249
644784 (dual-acting COX-2 inhibitor)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	acute and chronic pain conditions, including neuropathic pain	Phase I (888) 825-5249
842166 (non-cannabinoid CB2 agonist)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	inflammatory pain	Phase I (888) 825-5249
ABT-894	Abbott Laboratories Abbott Park, IL	neuropathic pain	Phase I (847) 937-6100
ABT-963	Abbott Laboratories Abbott Park, IL	pain	Phase I (847) 937-6100
<b>Accelanyl</b> <sup>™</sup> fentanyl effervescent buccal tablet	Cephalon West Chester, PA	breakthrough cancer pain	Phase III (610) 344-0200
ADL-8-7223 sterile lidocaine patch	Adolor Englewood Cliffs, NJ EpiCept Englewood Cliffs, NJ	post-incisional pain	Phase II (484) 595-1500 (201) 894-8980
ALGRX 3268	AlgoRx Pharmaceuticals Secaucus, NJ	pain	Phase III (201) 325-6900

## PAIN

Product Name	Sponsor	Indication	Development Status
ALGRX 4975	AlgoRx Pharmaceuticals <i>Secaucus, NJ</i>	pain	Phase II (201) 325-6900
alpha adrenergic agonist	Acadia Pharmaceuticals <i>San Diego, CA</i> Allergan <i>Irvine, CA</i>	neuropathic pain	Phase II (858) 558-2871 (714) 246-4500
AMG 517	Amgen <i>Thousand Oaks, CA</i>	pain	Phase I (805) 447-1000
<b>Arcoxia™</b> etoricoxib (MK-663)	Merck <i>Whitehouse Station, NJ</i>	acute pain	Phase III/ application submitted (800) 672-6372
AZD9272	AstraZeneca <i>Wilmington, DE</i>	neuropathic pain	Phase I (302) 886-3000
bicifadine	DOV Pharmaceutical <i>Hackensack, NJ</i>	pain	Phase III (201) 968-0980
<b>Cellegesic™</b> 0.4% nitroglycerin ointment	Cellegy Pharmaceuticals <i>Brisbane, CA</i>	pain reduction for chronic anal fissures	application submitted (650) 616-2200
CGX-1160	Cognetix <i>Salt Lake City, UT</i>	chronic intractable pain caused by spinal cord injury	Phase II (801) 581-0400
<b>Chronogesic®</b> sufentanil	DURECT <i>Cupertino, CA</i> Endo Pharmaceuticals <i>Chadds Ford, PA</i>	chronic pain (3-month continuous infusion subcutaneous treatment)	Phase II/III (408) 777-1417 (610) 558-9800
des-venafaxine succinate	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	neuropathic pain	Phase II (610) 902-1200
<b>Dyloject™</b> injectable diclofenac	Javelin Pharmaceuticals <i>Cambridge, MA</i>	post-operative pain	Phase II (617) 349-4500
<b>Dynastat</b> parecoxib	Pfizer <i>New York, NY</i>	pain management	application submitted (860) 732-5156
<b>Dysport®</b>	Ipsen <i>Milford, MA</i>	myofascial pain (see also other)	Phase II (508) 478-8900
<b>EN3202</b> oxymorphone hydrochloride (extended-release)	Endo Pharmaceuticals <i>Chadds Ford, PA</i> Penwest Pharmaceuticals <i>Danbury, CT</i>	moderate to severe pain in patients requiring continuous around-the-clock opioid therapy for an extended period of time	application submitted (610) 558-9800 (203) 796-3700
<b>EN3203</b> oxymorphone hydrochloride (immediate-release)	Endo Pharmaceuticals <i>Chadds Ford, PA</i>	acute moderate to severe pain	application submitted (610) 558-9800
<b>Gabapentin GR™</b>	Depomed <i>Menlo Park, CA</i>	post-herpetic pain	Phase II (650) 462-5900
hydromorphone	Altea Therapeutics <i>Tucker, GA</i>	acute and chronic pain	Phase I/II (678) 495-3100
hydromorphone (nasal therapy)	Intranasal Therapeutics <i>Lexington, KY</i>	acute and moderate to severe pain	Phase II (859) 252-5080

## PAIN

Product Name	Sponsor	Indication	Development Status
intranasal morphine gluconate	Nastech Pharmaceutical <i>Bothell, WA</i>	breakthrough cancer pain	Phase II (425) 908-3600
IP 751	Indevus Pharmaceuticals <i>Lexington, MA</i>	pain	Phase I (781) 402-3574
lacosamide	Schwarz Pharma <i>Milwaukee, WI</i>	neuropathic pain (see also epilepsy)	Phase III (800) 558-5114
levtofisopam	Vela Pharmaceuticals <i>Ewing, NJ</i>	neuropathic pain	Phase I (609) 771-8660
<b>Lidoderm®</b> lidocaine patch 5%	Endo Pharmaceuticals <i>Chadds Ford, PA</i>	chronic low back pain	Phase II (610) 558-9800
<b>LidoPAIN® BP</b>	Endo Pharmaceuticals <i>Chadds Ford, PA</i> EpiCept <i>Englewood Cliffs, NJ</i>	acute low back pain	Phase II (610) 558-9800 (201) 894-8980
MK0686	Merck <i>Whitehouse Station, NJ</i>	postherpetic neuralgia	Phase II (800) 672-6372
MP/DP	EpiCept <i>Englewood Cliffs, NJ</i>	dental pain	Phase II (201) 894-8980
<b>Namenda™</b> memantine HCl	Forest Laboratories <i>New York, NY</i>	neuropathic pain (see also Alzheimer's disease/ dementias)	Phase II (800) 947-5227
neramexane	Forest Laboratories <i>New York, NY</i>	chronic pain (see also Alzheimer's disease/ dementias)	Phase II (800) 947-5227
<b>Neurodex™</b>	Avanir Pharmaceuticals <i>San Diego, CA</i>	painful diabetic neuropathy (see also other)	Phase III (858) 622-5200
NGX-4010	NeurogesX <i>San Carlos, CA</i>	pain related to HIV-associated neuropathy, postherpetic neuralgia	Phase III (650) 508-2116
NP-1	EpiCept <i>Englewood Cliffs, NJ</i>	postherpetic neuralgia	Phase II completed (201) 894-8980
<b>OraVescent®</b> fentanyl	Cephalon <i>Frazer, PA</i>	breakthrough cancer pain	application submitted (610) 344-0200
OROS hydro-morphone (AP-77)	ALZA <i>Mountain View, CA</i>	pain	Phase III (650) 564-5000
<b>OxyNal™</b>	Elite Pharmaceuticals <i>Northvale, NJ</i>	abuse resistance product for use with oxycodone or other opioids	Phase I (201) 750-2646
<b>OxyQD™</b> oxycodone (once-daily)	Elite Pharmaceuticals <i>Northvale, NJ</i>	pain	Phase I (201) 750-2646
<b>Oxytrex™</b> oxycodone and low-dose naloxone	Pain Therapeutics <i>South San Francisco, CA</i>	chronic pain	Phase III (650) 624-8200
<b>PMI-150™</b> intranasal ketamine	Javelin Pharmaceuticals <i>Cambridge, MA</i>	acute moderate to severe pain	Phase II (617) 349-4500

## PAIN

Product Name	Sponsor	Indication	Development Status
post-operative pain depot (bupivacaine)	DURECT <i>Cupertino, CA</i>	post-operative pain	Phase II (408) 777-1417
<b>Prexige®</b> lumiracoxib (COX 189)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	pain	application submitted (888) NOW-NOVA
PW4142	Penwest Pharmaceuticals <i>Danbury, CT</i>	pain	Phase II (203) 796-3700
radafaxine (noradrenaline/ dopamine re-uptake inhibitor)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	neuropathic pain	Phase I (888) 825-5249
<b>Rapinyl™</b> fentanyl (sublingual)	Endo Pharmaceuticals <i>Chadds Ford, PA</i>	breakthrough cancer pain	Phase III (610) 558-9800
<b>Remoxy™</b> oxycodone	DURECT <i>Cupertino, CA</i> King Pharmaceuticals <i>Bristol, TN</i> Pain Therapeutics <i>South San Francisco, CA</i>	chronic pain	Phase III (408) 777-1417
REN-1654	Renovis <i>South San Francisco, CA</i>	neuropathic pain (sciatica)	Phase II (650) 266-1400
RGH-896	Forest Laboratories <i>New York, NY</i>	chronic pain	Phase II (800) 947-5227
<b>Rylomine™</b> intranasal morphine	Javelin Pharmaceuticals <i>Cambridge, MA</i>	acute pain	Phase II (617) 349-4500
[S,S]-reboxetine	Pfizer <i>New York, NY</i>	pain	Phase II (860) 732-5156
TC-2696	Targacept <i>Winston-Salem, NC</i>	pain	Phase I (336) 480-2100
topical ketoprofen patch	Endo Pharmaceuticals <i>Chadds Ford, PA</i>	localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains	Phase II (610) 558-9800
TQ-1017 tramadol extended-release (abuse deterrent)	Theraquest Biosciences <i>Blue Bell, PA</i>	pain	Phase I (610) 272-2071
transdermal sufentanil patch	DURECT <i>Cupertino, CA</i> Endo Pharmaceuticals <i>Chadds Ford, PA</i>	chronic pain	Phase II (408) 777-1417 (610) 558-9800
<b>Vicodin CR</b> hydrocodone/ acetaminophen	Abbott Laboratories <i>Abbott Park, IL</i>	pain	Phase III (847) 937-6100
XP13512 (gabapentin prodrug)	XenoPort <i>Santa Clara, CA</i>	post-herpetic neuralgia (see also other)	Phase II (408) 616-7200

## PARKINSON'S DISEASE

Product Name	Sponsor	Indication	Development Status
ACP-103	Acadia Pharmaceuticals <i>San Diego, CA</i>	treatment-induced dysfunction in Parkinson's disease	Phase II (858) 558-2871
adenosine 2a receptor antagonist	Schering-Plough <i>Kenilworth, NJ</i>	Parkinson's disease	Phase II (908) 298-4000
<b>Agilect®</b> rasagiline mesylate	Teva Pharmaceuticals North America <i>North Wales, PA</i>	Parkinson's disease (see also Alzheimer's/dementias)	application submitted (215) 591-3000
<b>Altropane®</b>	Boston Life Sciences <i>Boston, MA</i>	imaging agent for early diagnosis of Parkinson's disease	Phase III (617) 425-0200
CERE-120 (gene therapy)	Ceregene <i>San Diego, CA</i>	Parkinson's disease	Phase I (858) 458-8800
E2007	Eisai <i>Ridgefield Park, NJ</i>	Parkinson's disease (see also epilepsy, migraine, multiple sclerosis)	Phase II (888) 274-2378
fipamezole	Juvantia Pharma <i>Turku, Finland</i>	Parkinson's disease	Phase II <a href="http://www.juvantia.com">www.juvantia.com</a>
GPI 1485	MGI Pharma <i>Bloomington, MN</i> Symphony Neuro Development <i>Rockville, MD</i>	Parkinson's disease	Phase II (952) 346-4700 (301) 762-6119
<b>Kinampa</b> talampanel	IVAX <i>Miami, FL</i>	dyskinesia in Parkinson's disease	Phase II (305) 575-6000
KW-6002	Kyowa Pharmaceutical <i>Princeton, NJ</i>	Parkinson's disease	Phase III (609) 919-1100
melperone HCl	Ovation Pharmaceuticals <i>Deerfield, IL</i>	psychosis in Parkinson's disease	Phase II (800) 455-1141
<b>Neupro</b> rotigoline transdermal system	Schwarz Pharma <i>Milwaukee, WI</i>	Parkinson's disease	application submitted (800) 558-5114
NLX-P101 AAV-GAD	Neurologix <i>Fort Lee, NJ</i>	Parkinson's disease	Phase I (201) 592-6451
NS 2330	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	Parkinson's disease (see also Alzheimer's/dementias)	Phase II (203) 798-4700
<b>ReQuip®</b> ropinirole HCl (once-daily, controlled-release formulation)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	Parkinson's disease	Phase III (888) 825-5249
rotigotine nasal spray	Schwarz Pharma <i>Milwaukee, WI</i>	acute symptoms of Parkinson's disease	Phase I (800) 558-5114
SLV308	Solvay Pharmaceuticals <i>Marietta, GA</i>	Parkinson's disease	Phase III (770) 578-9000
<b>Spheramine™</b> human retinal pigment epithelial cells on microcarriers <b>(Orphan Drug)</b>	Titan Pharmaceuticals <i>South San Francisco, CA</i>	Parkinson's disease	Phase II (650) 244-4990

## PARKINSON'S DISEASE

Product Name	Sponsor	Indication	Development Status
SR 57667	sanofi-aventis <i>Bridgewater, NJ</i>	Parkinson's disease (see also Alzheimer's/dementias)	Phase II (800) 633-1610
V2006	Biogen Idec <i>Cambridge, MA</i>	Parkinson's disease	Phase II (617) 679-2000
<b>Zelapar™</b> selegiline	Valeant Pharmaceuticals <i>Costa Mesa, CA</i>	Parkinson's disease	application submitted (800) 548-5100

## RESTLESS LEGS SYNDROME

Product Name	Sponsor	Indication	Development Status
pramipexole	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	restless legs syndrome	in clinical trials (203) 798-4700
<b>ReQuip®</b> ropinirole HCl (extended release)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	restless legs syndrome	Phase III (888) 825-5249
rotigotine CDS	Schwarz Pharma <i>Milwaukee, WI</i>	restless legs syndrome	Phase III (800) 558-5114
XP13512 (gabapentin prodrug)	XenoPort <i>Santa Clara, CA</i>	restless legs syndrome (see also pain)	Phase II (408) 616-7200

## SLEEP DISORDERS

Product Name	Sponsor	Indication	Development Status
<b>Gaboxadol</b> GABA-A receptor agonist	Merck <i>Bridgewater, NJ</i>	sleep disorders	Phase III (800) 672-6372
indiplon	Pfizer <i>New York, NY</i> Neurocrine Biosciences <i>San Diego, CA</i>	insomnia	application submitted (201) 968-0980 (858) 617-7600
NG2-73	Neurogen <i>Branford, CT</i>	insomnia	Phase I (203) 488-8201
<b>Nuvigil™</b> armodafinil	Cephalon <i>West Chester, PA</i>	excessive sleepiness associated with narcolepsy, obstructive sleep apnea, shift work sleep disorder	application submitted (610) 344-0200
orexin receptor antagonist	Actelion Pharmaceuticals US <i>South San Francisco, CA</i>	sleep disorders	Phase II (650) 624-6900
Org 4419	Organon USA <i>West Orange, NJ</i>	obstructive sleep apnea	Phase II (973) 325-4500
Org 50081	Organon USA <i>West Orange, NJ</i>	sleep disorders	Phase II (973) 325-4500

## SPINAL CORD INJURY

Product Name	Sponsor	Indication	Development Status
A2A agonist	Adenosine Therapeutics <i>Charlottesville, VA</i>	spinal cord injury	in clinical trials (434) 220-9400
<b>Cethrin®</b>	BioAxone Therapeutic <i>Montreal, Quebec</i>	acute thoracic and cervical spinal cord injury	Phase I/II (514) 282-9990
fampridine-SR	Acorda Therapeutics <i>Hawthorne, NY</i>	chronic spinal cord injury (see also multiple sclerosis)	Phase III completed (914) 347-4300
HP184	sanofi-aventis <i>Bridgewater, NJ</i>	spinal cord injury	Phase II (800) 633-1610
<b>ProCord</b> incubated macrophages (cell therapy)	Proneuron Biotechnologies <i>Los Angeles, CA</i>	spinal cord injury	Phase II/III <a href="http://www.proneuron.com">www.proneuron.com</a>

## STROKE

Product Name	Sponsor	Indication	Development Status
234551 (endothelin A antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> Shionogi USA <i>Florham Park, NJ</i>	stroke	Phase I/II (888) 825-5249
737004 (S-0139) (endothelin A antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> Shionogi USA <i>Florham Park, NJ</i>	stroke	Phase I/II (888) 825-5249
<b>Cerebril™</b>	Neurochem <i>Laval, Quebec</i>	hemorrhagic stroke due to cerebral amyloid angiopathy	Phase II completed (450) 680-4500
clazosentan	Actelion Pharmaceuticals US <i>South San Francisco, CA</i>	prevention of vasospasm following aneurismal subarachnoid hemorrhage	Phase II/III (650) 624-6900
desmoteplase	Forest Laboratories <i>New York, NY</i>	ischemic stroke	Phase III (800) 947-5227
E2051	Eisai <i>Ridgefield Park, NJ</i>	stroke	Phase I (888) 274-2378
LJP-1082	La Jolla Pharmaceutical <i>San Diego, CA</i>	antibody-mediated stroke resulting from antiphospholipid syndrome	Phase I/II completed (858) 452-6600
MC-1	Medicure <i>Winnipeg, Manitoba</i>	stroke	Phase I (204) 487-7412
NXY-059	AstraZeneca <i>Wilmington, DE</i> Renovis <i>South San Francisco, CA</i>	acute ischemic stroke	Phase III (302) 886-3000

## STROKE

Product Name	Sponsor	Indication	Development Status
ONO-2506	Merck <i>Whitehouse Station, NJ</i>	stroke	Phase II (800) 672-6372
SUN N4057 piclozotan	Daiichi Asubio Pharmaceuticals <i>Rochelle Park, NJ</i>	acute ischemic stroke	Phase II (201) 368-5020
SUN N8075	Daiichi Asubio Pharmaceuticals <i>Rochelle Park, NJ</i>	stroke	Phase I (201) 368-5020
<b>Viprinex™</b> ancrod	Neurobiological Technologies <i>Richmond, CA</i>	ischemic stroke	Phase III (510) 262-1730

## OTHER

Product Name	Sponsor	Indication	Development Status
<b>Ampalex®</b> CX516	Cortex Pharmaceuticals <i>Irvine, CA</i>	autism (see also Alzheimer's)	Phase II completed (949) 727-3157
<b>Avonex®</b> interferon beta-1a	Biogen Idec <i>Cambridge, MA</i>	chronic inflammatory demyelinating polyneuropathy	Phase II (617) 679-2000
<b>Botox®</b> botulinum toxin type A	Allergan <i>Irvine, CA</i>	juvenile cerebral palsy	Phase II/III (800) 433-8871
<b>CellCept</b> mycophenolate mofetil	Aspreva Pharmaceuticals <i>Victoria, BC</i> Roche <i>Nutley, NJ</i>	myasthenia gravis	Phase III (250) 744-2488 (973) 235-5000
clobazam	Ovation Pharmaceuticals <i>Deerfield, IL</i>	Lennox-Gastaut syndrome in pediatrics and adults	Phase II (800) 455-1141
Cop-1 neuroprotective vaccine	Proneuron Biotechnologies <i>Los Angeles, CA</i>	CNS disorders	Phase I/II <a href="http://www.proneuron.com">www.proneuron.com</a>
<b>Dysport®</b>	Ipsen <i>Milford, MA</i>	cervical dystonia (see also pain)	Phase III (508) 478-8900
edratide	Teva Pharmaceuticals North America <i>North Wales, PA</i>	systemic lupus erythematosus	Phase II (215) 591-3000
<b>Neurodex™</b>	Avanir Pharmaceuticals <i>San Diego, CA</i>	pseudobulbar affect (emotional lability)—pathological laughing or crying associated with neurologic disorders (see also pain)	Phase III (858) 622-5200
<b>NeuroSTAT</b>	Maas BiolAB <i>Albuquerque, NM</i>	battlefield traumatic brain injuries	in clinical trials
pagoclone	Indevus Pharmaceuticals <i>Lexington, MA</i>	stuttering	Phase II (781) 861-8444
PN401	Wellstat BioPharma <i>Gaithersburg, MD</i>	neurogenerative disease	Phase I (240) 631-2500

## OTHER

Product Name	Sponsor	Indication	Development Status
Rituxan® rituximab	Biogen Idec Cambridge, MA Genentech South San Francisco, CA	systemic lupus erythematosus (see also multiple sclerosis)	Phase II/III (617) 679-2000 (650) 225-1000
SNT-MC17 idebenone	Santhera Pharmaceuticals Liestal, Switzerland National Institutes of Health Bethesda, MD	Friedreich's ataxia	Phase III <a href="http://www.santhera.com">www.santhera.com</a>
SR 57746 xaliproden	sanofi-aventis Bridgewater, NJ	chemotherapy-induced neuropathies (see also Alzheimer's/dementias)	Phase III (800) 633-1610
TACI-Ig	Serono Rockland, MA	systemic lupus erythematosus	Phase II (800) 283-8088
XP19986 (R-baclofen prodrug)	XenoPort Santa Clara, CA	spasticity	Phase I (408) 616-7200
XY2405	Xytis Pharmaceuticals San Mateo, CA	traumatic brain injury	Phase II <a href="http://www.xytis.com">www.xytis.com</a>

The content of this survey has been obtained through government sources, industry sources, and the "Adis R&D Insight" database based on the latest information. Survey current as of **February 28, 2006**. The information may not be comprehensive. For more specific information about a particular product, contact the individual company directly or go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov). The entire series of *Medicines in Development* is available on PhRMA's web site.

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**Alzheimer's disease**—Progressive and rarely reversible chronic deterioration of all mental functions.

**amyotrophic lateral sclerosis (ALS)**—Also known as Lou Gehrig's disease, the most common of the motor neuron diseases, a group of rare disorders in which the nerves that control muscular activity degenerate within the brain and spinal cord causing weakness and wasting of the muscles.

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

**astrocytoma**—A type of malignant brain tumor. Astrocytomas are the most common type of **glioma**, a tumor arising from the glial (supporting) cells within the nervous system.

**cerebral amyloid angiopathy (CAA)**—CAA is defined by a particular kind of protein deposit (amyloid) in the walls of blood vessels that take blood to the brain. CAA is a common process in aging and usually harmless. In some people with severe CAA, however, the protein deposits cause the blood vessel walls to crack and blood to leak out, causing a bleeding (or **hemorrhagic**) **stroke**.

**cerebral palsy**—A general term for disorders of movement and posture resulting from damage to the brain in pregnancy, during birth, in the newborn period or in early childhood.

**cervical dystonia**—Disorder or lack of tone in the muscles of the neck.

**dementia**—Degeneration of central nervous functions, such as memory and learning capacity. The natural decline of these functions with age is grossly exaggerated in dementia.

**epilepsy**—Recurrent seizures—transient neurological abnormalities caused by abnormal electrical activity in the brain—or temporary alteration in one or more brain functions. Seizures are a symptom of brain dysfunction and can result from a wide variety of diseases or injury.

**Friedreich's ataxia**—An inherited disease that causes progressive damage to the nervous system resulting in symptoms ranging from gait disturbance and speech problems to heart disease. "Ataxia," which refers to coordination problems such as clumsy or awkward movements and unsteadiness, occurs in many different diseases and conditions.

**glioblastoma multiforme**—The most common and most malignant of the **astrocytomas**. The tumor grows so fast that it increases pressure in the brain, producing headaches, slowed thinking, and if severe enough, sleepiness and coma.

**glioma**—A type of brain tumor arising from the supporting glial cells within the brain. Gliomas make up about 60 percent of all primary brain tumors.

**Huntington's disease**—Huntington's chorea is an uncommon, inherited disease in which degeneration of the basal ganglia (structures deep in the brain) results in chorea (rapid, jerky, involuntary movements) and dementia (progressive mental impairment).

**Lennox-Gastaut syndrome**—Characterized by seizures and mental retardation in infants and young children.

**medulloblastoma**—The most common primary central nervous system tumor which arises in childhood. Medulloblastomas arise in the fourth ventricle, between the brain stem and the cerebellum. Common symptoms are unsteadiness, headaches, and vomiting due to hydrocephalus (from blockage of cerebrospinal fluid flow).

**meningioma**—A type of tumor that develops from the meninges, the membrane that surrounds the brain and spinal cord. Most meningiomas (90 percent) are categorized as benign tumors, with the remaining 10 percent being atypical or malignant. However, the word "benign" can be misleading in this case, because when benign tumors grow and constrict and affect the brain, they can cause disability and even be life-threatening.

**metastases/metastatic**—Areas of secondary cancer that have spread from the primary or original cancer site.

**migraine headache**—Severe headache resulting from an abnormal dilation of blood vessels deep within the brain. It can last from two hours to several days and is often accompanied by nausea, vomiting and sensitivity to noise and/or light.

**multiple sclerosis (MS)**—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. Symptoms range from numbness and tingling to paralysis and incontinence.

**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.

**narcolepsy**—Chronic, excessive daytime sleepiness and episodes of sleep recurring several times a day, which last from a few seconds to about 15 minutes.

**neuroblastoma**—A tumor of the adrenal glands or sympathetic nervous system (the part of the nervous system responsible for certain automatic body functions, such as the control of heart rate). Neuroblastomas are the most common extracranial (outside the skull) solid tumors of childhood.

**neurofibromatosis**—The neurofibromatoses are genetic disorders of the nervous system that primarily affect the development and growth of neural (nerve) cell tissues. These disorders cause tumors to grow on nerves and produce other abnormalities such as skin changes and bone deformities.

**neuropathies**—Abnormal and usually degenerative state of the nervous system or nerves. The term can also refer to systemic conditions, such as muscular atrophy, that stem from neuropathies.

**Parkinson's disease**—Chronic neurologic disease of unknown cause, characterized by tremors, rigidity and an abnormal gait.

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

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

**Phase III**—Extensive clinical trials in humans.

**post-herpetic neuralgia**—A burning pain that may recur at the site of an attack of shingles months or even years after the illness.

**restless legs syndrome**—Restless legs syndrome is an overwhelming urge to move the legs usually caused by uncomfortable or unpleasant sensations in the legs.

**spinal cord injury**—Damage to the spinal cord which can cause loss of sensation, muscle weakness or paralysis.

**stroke**—Usually caused by atherosclerosis. It results in death or serious brain damage, such as paralysis or loss of speech. An **ischemic stroke** is caused by blocked or narrowed arteries that prevent sufficient blood and oxygen from reaching the brain.

# SELECTED FACTS ABOUT NEUROLOGIC DISORDERS IN THE UNITED STATES

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## Alzheimer's Disease/Dementias<sup>1</sup>

- Some 4.5 million Americans have **Alzheimer's disease (AD)**. By 2050, the estimated range of AD prevalence will be 11.3 million to 16 million Americans, unless a cure or prevention is found.
  - U.S. society spends at least \$100 billion a year on **AD**.
- 

## Brain Tumors<sup>2</sup>

- In 2004, an estimated 40,900 new cases of primary brain tumors (both malignant and benign) were diagnosed.
  - Approximately 3,140 American children (younger than age 20) are diagnosed annually with primary brain tumors, which are the most common form of solid tumors in children and the second most frequent malignancy of childhood. Brain tumors are the second leading cause of cancer-related deaths in children.
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## Epilepsy<sup>3</sup>

- More than 2 million people in the United States—about 1 in 100—have experienced an unprovoked seizure or have been diagnosed with epilepsy. For about 80 percent of those people, seizures can be controlled with modern medicines and surgery, but about 20 percent of them have intractable epilepsy.
  - About 20 percent of seizures in children are due to cerebral palsy or other neurological abnormalities.
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## Head Injury<sup>4</sup>

- Each year, 1.5 million Americans sustain a traumatic brain injury (TBI)—that's one person injured every 21 seconds. The risk of TBI is highest among adolescents, young adults and those older than age 75. More than 50,000 people die each year as a result of brain injury.
  - The direct medical costs and indirect costs of TBI totaled an estimated \$56.3 billion in 1995.
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## Huntington's Disease<sup>3</sup>

- About 30,000 people in the United States have Huntington's disease (HD). Its estimated prevalence is about 1 in every 10,000 people. Today, at least 150,000 people have a 50 percent risk of developing HD, and thousands more of their relatives live with the possibility that they, too, might develop HD.
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## Migraine<sup>5</sup>

- Approximately 28 million people—about 13 percent of the U.S. population—suffer from migraines. While migraines afflict both men and women, three times more women than men experience them.
  - An estimated 157 million workdays are lost annually because of the pain and associated symptoms of migraine, which costs U.S. employers \$13 billion a year in missed work and reduced productivity.
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## Multiple Sclerosis<sup>6</sup>

- Some 400,000 Americans have multiple sclerosis (MS), and every week another 200 are diagnosed. Up to three times as many women as men have MS. Most people are diagnosed between the ages of 20 and 50.
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## Neuropathies

- People with **diabetes** can develop nerve problems at any time, but significant clinical neuropathy can develop within the first 10 years after diagnosis. Some 60 percent of patients have some form of neuropathy, but in 30 percent to 40 percent of cases there are no symptoms.<sup>7</sup>
  - **Peripheral neuropathy** affects at least 20 million people in this country<sup>8</sup>
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## Pain<sup>7</sup>

- The majority of U.S. adults—57 percent—have experienced **chronic** or recurrent pain in the past year.
  - Pain costs an estimated \$100 billion each year. In 1996, more than \$50 billion was spent on the diagnosis and treatment of **back pain** alone.
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# SELECTED FACTS ABOUT NEUROLOGIC DISORDERS IN THE UNITED STATES

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## Parkinson's Disease

- Today, 1.5 million Americans have PD, and each year 60,000 new cases are diagnosed.<sup>9</sup> A new case of Parkinson's is diagnosed in this country every nine minutes.<sup>10</sup>
  - PD is estimated to cost the nation about \$25 billion annually.<sup>11</sup>
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## Sleep Disorders<sup>12</sup>

- **Insomnia** affects more than 70 million Americans. Chronic or severe insomnia affects up to 15 percent of adults.
  - Some 12 million Americans experience **restless legs syndrome**, which increases with age. Older people experience symptoms more frequently and for longer periods of time.
  - Sleep deprivation and **sleep disorders** are estimated to cost Americans more than \$100 billion annually in lost productivity, medical expenses, sick leave, and property and environmental damage.
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## Spinal Cord Injury<sup>13</sup>

- The estimated annual incidence of spinal cord injury (SCI), not including those who die at an accident scene, is approximately 11,000 new cases each year in the United States. The estimated number of people living today with SCI ranges from 225,000 to 288,000.
  - The costs for those living with SCI vary greatly according to injury severity. For example, the lifetime direct medical costs are more than \$2 million for someone with high quadriplegia injured at age 25, compared with the more than \$600,000 it will cost someone injured at the same age who has incomplete motor functions.
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## Stroke<sup>14</sup>

- About 700,000 Americans will have a stroke this year—that's someone every 45 seconds. In adults over age 55, the lifetime risk for stroke is greater than 1 in 6.
  - Stroke accounted for more than 1 of every 15 deaths in the United States in 2002. On average, every three minutes someone dies of a stroke.
  - The direct and indirect costs of stroke are estimated to be \$56.8 billion in 2005.
- 

## Other

- More than 4,500 American infants are diagnosed each year with **cerebral palsy**. Birth complications account for probably less than 10 percent of these cases. About 10 percent to 20 percent of American children acquire the disorder after birth as a result of brain infections or injuries.<sup>3</sup>
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## Sources:

1. Alzheimer's Association ([www.alz.org](http://www.alz.org))
2. American Brain Tumor Association ([www.abta.org](http://www.abta.org))
3. National Institute of Neurological Disorders and Stroke ([www.ninds.nih.gov](http://www.ninds.nih.gov))
4. Brain Injury Association of America ([www.biausa.org](http://www.biausa.org))
5. National Headache Foundation ([www.headaches.org](http://www.headaches.org))
6. National Multiple Sclerosis Society ([www.nationalmssociety.org](http://www.nationalmssociety.org))
7. American Pain Foundation ([www.painfoundation.org](http://www.painfoundation.org))
8. neurologychannel ([www.neurologychannel.com](http://www.neurologychannel.com))
9. National Parkinson Foundation ([www.parkinson.org](http://www.parkinson.org))
10. St. Mary's Health Care ([www.smmmc.org](http://www.smmmc.org))
11. Parkinson's Action Network ([www.parkinsonsaction.org](http://www.parkinsonsaction.org))
12. National Sleep Foundation ([www.sleepfoundation.org](http://www.sleepfoundation.org))
13. Spinal Cord Injury Information Network ([www.spinalcord.uab.edu](http://www.spinalcord.uab.edu))
14. American Heart Association ([www.americanheart.org](http://www.americanheart.org))

## THE DRUG DISCOVERY, DEVELOPMENT AND APPROVAL PROCESS

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

Discovery/ Preclinical Testing		Clinical Trials			FDA	Phase IV
		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 \$802 million to get one new medicine from the laboratory to U.S. patients, according to a November 2001 report by the Tufts Center for the Study of Drug Development.

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

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

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

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

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

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

**New Drug Application (NDA)/Biologic License Application (BLA).** Following the completion of all three phases of clinical trials, a company analyzes all of the data and files an NDA or BLA with FDA if the data successfully demonstrate both safety and effectiveness. The applications contain all of the scientific information that the company has gathered. Applications typically run 100,000 pages or more. The average review time for the 36 new therapeutics approved by the FDA in 2004 was 18.1 months.

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

Discovering and developing safe and effective new medicines is a long, difficult, and expensive process. PhRMA member companies invested an estimated \$39.4 billion in research and development in 2005.

*Medicines in Development for Neurologic Disorders* is presented by PhRMA in cooperation with the following organizations:

The ALS Association  
American Academy of Physician Assistants  
American Brain Tumor Association  
American Headache Society  
American Nurses Association  
American Pain Foundation  
American Pain Society  
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