

Neurological Disorders

PRESENTED BY AMERICA'S PHARMACEUTICAL RESEARCH COMPANIES

Pharmaceutical Companies Researching and Developing More Than 500 Medicines for Neurological Disorders

America's pharmaceutical research companies are developing 547 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 more than \$148 billion annually, according to the Alzheimer's Association.

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

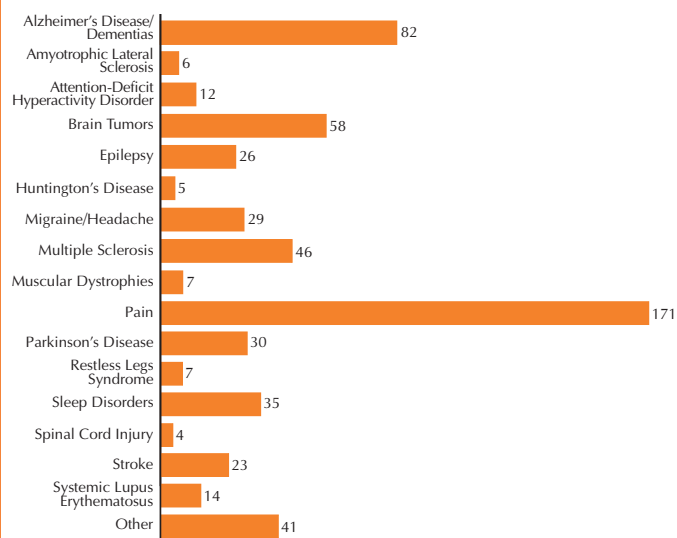
- 171 medicines for pain for the 76.5 million U.S. adults having experienced chronic or recurrent pain.
- 82 medicines for Alzheimer's disease, which afflicts more than 5 million Americans.
- 58 medicines for brain tumors, for the estimated 359,000 Americans who have a primary brain tumor.
- 46 medicines for multiple sclerosis, which afflicts some 400,000 Americans.
- 30 medicines for Parkinson's disease, which affects as many as 1.5 million Americans.
- 29 medicines for migraine, a condition that affects about 29.5 million people.
- 26 medicines for epilepsy, which affects more than 3 million Americans.
- 23 medicines for stroke, the third leading cause of death after heart disease and cancer.

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.
- A medicine for glioblastoma (brain cancer) that singles out and latches onto the receptors on the surface of

MEDICINES IN DEVELOPMENT FOR NEUROLOGICAL DISORDERS*



*Some medicines are listed in more than one category.

the malignant cells—but not the healthy cells—and destroys them.

- A medicine in development for epilepsy activates certain proteins in the brain that play a role in regulating both the resting potential and electrical firing of nerve cells in the brain.

The new medicines now in the research pipeline will add to the substantial progress made in previous years by pharmaceutical and biotechnology companies in developing new and more effective neurological 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 pharmaceutical research 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 Neurological Disorders

ALZHEIMER'S DISEASE/DEMENTIAS

| Product Name | Sponsor | Indication | Development Status* |
|--|--|--|--|
| 239512 (histamine H3 receptor antagonist) | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | dementia | Phase I (888) 825-5249 |
| 742457 (5HT6 receptor antagonist) | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | dementia associated with Alzheimer's disease | Phase II (888) 825-5249 |
| 933776 | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | Alzheimer's disease | Phase I (888) 825-5249 |
| ABT-107 | Abbott Laboratories Abbott Park, IL | cognition disorders (see also other) | Phase I (847) 937-6100 |
| ABT-560 | Abbott Laboratories Abbott Park, IL | cognition disorders, dementia | Phase I (847) 937-6100 |
| AC-1202 | Accera Broomfield, CO | mild-to-moderate Alzheimer's disease | Phase II (303) 439-0004 |
| ACC-001 | Wyeth Collegeville, PA Elan New York, NY | Alzheimer's disease | Phase II (800) 934-5556 (212) 407-5740 |
| Agilect [®] rasagiline mesylate | Teva Pharmaceuticals USA North Wales, PA | Alzheimer's disease | Phase II (215) 591-3000 |
| AL-108 | Allon Therapeutics Vancouver, BC | Alzheimer's disease | Phase II (604) 736-0634 |
| AL-208 | Allon Therapeutics Vancouver, BC | mild cognitive impairment | Phase II (604) 736-0634 |
| Alzhemed [™] tramiprosate | Neurochem Laval, QC | Alzheimer's disease | Phase III (866) 680-4456 |
| Aricept [®] donepezil hydrochloride | Eisai Ridgefield Park, NJ Pfizer New York, NY | cognitive symptoms associated with Down's syndrome | Phase III (888) 274-2378 |
| arundic acid | Merck Whitehouse Station, NJ | Alzheimer's disease (see also stroke) | Phase II (800) 672-6372 |
| AV965 | Avera Pharmaceuticals San Diego, CA | Alzheimer's disease, cognition disorders | Phase I (858) 847-0650 |
| AVE8112 | sanofi-aventis Bridgewater, NJ | Alzheimer's disease | Phase I (800) 633-1610 |

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

ALZHEIMER'S DISEASE/DEMENTIAS

| Product Name | Sponsor | Indication | Development Status |
|---|---|---|---|
| AZD-103 (ELND005) | Elan New York, NY Transition Therapeutics Toronto, ON | Alzheimer's disease | Phase II (212) 407-5740 (416) 260-7770 |
| AZD0328 | AstraZeneca Wilmington, DE | Alzheimer's disease | Phase I (800) 236-9933 |
| bapineuzumab (AAB-001) | Elan Pharmaceuticals New York, NY Wyeth Pharmaceuticals Collegeville, PA | Alzheimer's disease (intravenous) | Phase III (212) 407-5740 (800) 934-5556 |
| | | Alzheimer's disease (subcutaneous) | Phase I (212) 407-5740 (800) 934-5556 |
| begacestat | Wyeth Pharmaceuticals Collegeville, PA | Alzheimer's disease | Phase I (610) 902-1200 |
| C9138 | Merck Whitehouse Station, NJ | Alzheimer's disease | Phase I (800) 672-6372 |
| CAD-106 | CytosBiotechnology Postfach, Switzerland Novartis Pharmaceuticals East Hanover, NJ | Alzheimer's disease | Phase I (888) 669-6682 |
| CERE-110 (growth factor gene therapy) | Ceregene San Diego, CA | Alzheimer's disease | Phase I (858) 458-8800 |
| Corlux™ mifepristone | Corcept Therapeutics Menlo Park, CA | Alzheimer's disease (see also brain tumors) | Phase II (650) 327-3270 |
| CTS-21166 | CoMentis South San Francisco, CA | Alzheimer's disease | Phase I (650) 359-2600 |
| CX717 | Cortex Pharmaceuticals Irvine, CA | Alzheimer's disease (see also sleep disorders) | Phase II (949) 727-3157 |
| DAR-100 | DarPharma Chapel Hill, NC | cognition disorders (see also Parkinson's disease) | Phase II (919) 403-4348 |
| DAS-431 (intravenous) | DrugAbuse Sciences Hayward, CA | cognition disorders | Phase I (510) 259-3200 |
| docosahexaenoic acid | Martek Biosciences Columbia, MD | Alzheimer's disease | Phase III (410) 740-0081 |
| EVP-6124 | EnVivo Pharmaceuticals Watertown, MA | Alzheimer's disease | Phase I (617) 225-4250 |
| Exelon® rivastigmine | Novartis Pharmaceuticals East Hanover, NJ | vascular dementia | Phase III (888) 669-6682 |
| Flurizan™ tarenflurbil | Myriad Pharmaceuticals Salt Lake City, UT | Alzheimer's disease | Phase III (801) 584-3600 |
| gamma secretase inhibitor | Bristol-Myers Squibb Princeton, NJ | Alzheimer's disease | Phase I (212) 546-4000 |
| GTS 21 | CoMentis South San Francisco, CA | Alzheimer's disease (see also attention-deficit hyperactivity disorder) | Phase II (650) 869-7600 |

ALZHEIMER'S DISEASE/DEMENTIAS

| Product Name | Sponsor | Indication | Development Status |
|--|---|--|---|
| HT-0712 | Helicon Therapeutics <i>Farmingdale, NY</i> | cognition disorders | Phase II (631) 370-8818 |
| huperzine A | Neuro-Hitech <i>New York, NY</i> | Alzheimer's disease | Phase I (212) 594-1225 |
| immune globulin (IVIG) | Baxter Healthcare <i>Deerfield, IL</i> | Alzheimer's disease | Phase II (800) 422-9837 |
| ispronicleline (TC-1734) | AstraZeneca <i>Wilmington, DE</i> Targacept <i>Winston-Salem, NC</i> | Alzheimer's disease, cognitive disorders | Phase II (800) 236-9933 |
| L830982 | Merck <i>Whitehouse Station, NJ</i> | cognition disorders | Phase II (800) 672-6372 |
| lecozotan (SRA333) | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | Alzheimer's disease | Phase II (800) 934-5556 |
| leuprolide acetate (VP-4896) | Voyager Pharmaceuticals <i>Raleigh, NC</i> | Alzheimer's disease | Phase III (919) 846-4880 |
| Lipitor [®] atorvastatin | Pfizer <i>New York, NY</i> | Alzheimer's disease | Phase III (860) 732-5156 |
| LY450139 | Eli Lilly <i>Indianapolis, IN</i> | Alzheimer's disease | Phase II (800) 545-5979 |
| LY451395 | Eli Lilly <i>Indianapolis, IN</i> | Alzheimer's disease | Phase II (800) 545-5979 |
| LY2062430 | Eli Lilly <i>Indianapolis, IN</i> | Alzheimer's disease | Phase II (800) 545-5979 |
| Marinol [®] dronabinol | Unimed Pharmaceuticals <i>Marietta, GA</i> | dementia | Phase II |
| MEM-1003 | Memory Pharmaceuticals <i>Montvale, NJ</i> | Alzheimer's disease | Phase II (201) 802-7100 |
| | | mild cognitive impairment, vascular dementia | Phase I (201) 802-7100 |
| MEM-1414 | Memory Pharmaceuticals <i>Montvale, NJ</i> | Alzheimer's disease, mild cognitive impairment | Phase I (201) 802-7100 |
| MEM-3454 | Memory Pharmaceuticals <i>Montvale, NJ</i> | Alzheimer's disease | Phase II (201) 802-7100 |
| MEM-63908 (R4996) | Memory Pharmaceuticals <i>Montvale, NJ</i> Roche <i>Nutley, NJ</i> | Alzheimer's disease | Phase I (201) 802-7100 (973) 235-5000 |
| Memryte [™] leuprorelin implant | DURECT <i>Cupertino, CA</i> Voyager Pharmaceuticals <i>Raleigh, NC</i> | Alzheimer's disease | Phase III (919) 846-4880 |
| MK-0249 | Merck <i>Whitehouse Station, NJ</i> | Alzheimer's disease | Phase II (800) 672-6372 |

ALZHEIMER'S DISEASE/DEMENTIAS

| Product Name | Sponsor | Indication | Development Status |
|--|--|--|---|
| MK-0752 | Merck <i>Whitehouse Station, NJ</i> | Alzheimer's disease | Phase I (800) 672-6372 |
| MK-0952 | Merck <i>Whitehouse Station, NJ</i> | Alzheimer's disease | Phase I (800) 672-6372 |
| Motiva™ nefiracetam | Neuren Pharmaceuticals <i>Bethesda, MD</i> | dementia | Phase II (301) 941-1830 |
| neramexane | Forest Laboratories <i>New York, NY</i> | 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 |
| NIC5-15 | Humanetics <i>Eden Prairie, MN</i> | Alzheimer's disease | Phase II (952) 937-7660 |
| N-PEP-12 | Ebewe <i>Unterach, Austria</i> | cognition disorders | Phase I |
| Nuvigil™ armodafinil | Cephalon <i>Frazer, PA</i> | cognition disorders | Phase II (610) 344-0200 |
| Oxigon™ indolepropionic acid derivative | Intellect Neurosciences <i>New York, NY</i> | Alzheimer's disease | Phase I (212) 448-9300 |
| PAZ-417 | Wyeth <i>Collegeville, PA</i> | Alzheimer's disease | Phase I (800) 934-5566 |
| PF-3084014 | Pfizer <i>New York, NY</i> | Alzheimer's disease | Phase I (860) 732-5156 |
| PF-4360365 | Pfizer <i>New York, NY</i> | Alzheimer's disease | Phase II (860) 732-5156 |
| Posiphen™ R-phenserine | TorreyPines Therapeutics <i>La Jolla, CA</i> | Alzheimer's disease | Phase I (858) 623-5665 |
| PRX-03140 | EPIX Pharmaceuticals <i>Lexington, MA</i> | Alzheimer's disease | Phase I (781) 761-7600 |
| PRX-07034 | EPIX Pharmaceuticals <i>Lexington, MA</i> | Alzheimer's disease, cognition disorders | Phase I (781) 761-7600 |
| R1450 | Roche <i>Nutley, NJ</i> | Alzheimer's disease | Phase I (973) 235-5000 |
| R4996 (MEM-63908) | Memory Pharmaceuticals <i>Montvale, NJ</i> Roche <i>Nutley, NJ</i> | Alzheimer's disease | Phase I (201) 802-7100 (973) 235-5000 |
| rosiglitazone XR | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | Alzheimer's disease | Phase III (888) 825-5249 |
| safinamide | EMD Serono <i>Rockland, MA</i> | Alzheimer's disease (see also Parkinson's disease, restless legs syndrome) | Phase I (800) 283-8088 |
| SAM-315 | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | Alzheimer's disease | Phase I (800) 934-5556 |

ALZHEIMER'S DISEASE/DEMENTIAS

| Product Name | Sponsor | Indication | Development Status |
|--------------------------------|--|---|--|
| SAM-531 | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | Alzheimer's disease | Phase I (800) 934-5556 |
| selegiline transdermal | Somerset Pharmaceuticals <i>Tampa, FL</i> | Alzheimer's disease (see also attention-deficit hyperactivity disorder, Parkinson's disease) | Phase III |
| | | ----- cognition disorders | Phase II |
| Sermion® nicergoline | Pfizer <i>New York, NY</i> | Alzheimer's disease | Phase III (860) 732-5156 |
| SGS518 | Saegis Pharmaceuticals <i>Half Moon Bay, CA</i> | mild cognitive impairment | Phase II (650) 560-1210 |
| SGS742 | Saegis Pharmaceuticals <i>Half Moon Bay, CA</i> | Alzheimer's disease, mild cognitive impairment (see also attention-deficit hyperactivity disorder) | Phase II (650) 560-1210 |
| SSR180711 | sanofi-aventis <i>Bridgewater, NJ</i> | Alzheimer's disease | Phase I (800) 633-1610 |
| SYN-114 | Roche <i>Nutley, NJ</i> Synosia Therapeutics <i>South San Francisco, CA</i> | cognition disorders | Phase I (973) 235-5000 (650) 244-4850 |
| T-817MA | Toyama Chemical <i>Tokyo, Japan</i> | Alzheimer's disease | Phase I |
| Tanakan® EGb 761 | Ipsen <i>Milford, MA</i> | Alzheimer's disease | Phase III (508) 478-8900 |
| TTP488 (PF-4494700) | Pfizer <i>New York, NY</i> TransTech Pharma <i>High Point, NC</i> | Alzheimer's disease (see also pain) | Phase II (860) 732-5156 (336) 841-0300 |
| V950 | Merck <i>Whitehouse Station, NJ</i> | Alzheimer's disease | Phase I (800) 672-6372 |

AMYOTROPHIC LATERAL SCLEROSIS

| Product Name | Sponsor | Indication | Development Status |
|-------------------------------------|--|--|-----------------------------|
| AEOL 10150 | Aeolus Pharmaceuticals <i>Laguna Niguel, CA</i> | amyotrophic lateral sclerosis (ALS) | Phase I (949) 481-9825 |
| arimoclomol | Cytrx <i>Los Angeles, CA</i> | ALS | Phase II (310) 826-5648 |
| creatine monohydrate (ALS-02) | Avicena <i>Palo Alto, CA</i> | ALS (see also Huntington's disease, muscular dystrophies, Parkinson's disease, other) | Phase III (415) 397-2880 |

AMYOTROPHIC LATERAL SCLEROSIS

| Product Name | Sponsor | Indication | Development Status |
|-----------------------------|---|------------|-------------------------------|
| KNS-760704 | Knopp Neurosciences <i>Pittsburgh, PA</i> | ALS | Phase I (412) 488-1776 |
| Myogane™ PYM50018 | Phytopharm <i>Cambridgeshire, United Kingdom</i> | ALS | Phase I www.phytopharm.com |
| TRO-19622 | Trophos <i>Cedex, France</i> | ALS | Phase I |

ATTENTION-DEFICIT HYPERACTIVITY DISORDER

| Product Name | Sponsor | Indication | Development Status |
|-------------------------------------|---|--|---|
| 372475 | GlaxoSmithKline <i>Philadelphia, PA Rsch. Triangle Park, NC</i> | attention-deficit hyperactivity disorder (ADHD) | Phase II (888) 825-5249 |
| ABT-089 | Abbott Laboratories <i>Abbott Park, IL</i> | ADHD | Phase II (847) 937-6100 |
| ABT-894 | Abbott Laboratories <i>Abbott Park, IL</i> | ADHD (see also pain) | Phase II (847) 937-6100 |
| clonidine controlled-release | Addrenex Pharmaceuticals <i>Durham, NC Sciele Pharma Atlanta, GA</i> | ADHD | Phase III (919) 941-0800 (800) 461-3696 |
| Concerta® methylphenidate | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> | ADHD in adults | application submitted (800) 817-5286 |
| GTS 21 | CoMentis <i>South San Francisco, CA</i> | ADHD (see also Alzheimer's disease) | Phase I (650) 869-7600 |
| LY-2216684 | Eli Lilly <i>Indianapolis, IN</i> | ADHD | Phase I (800) 545-5979 |
| PF-3654746 | Pfizer <i>New York, NY</i> | ADHD | Phase I (860) 732-5156 |
| selegiline transdermal | Somerset Pharmaceuticals <i>Tampa, FL</i> | ADHD (see also Alzheimer's disease, Parkinson's disease) | Phase I |
| SGS742 | Saegis Pharmaceuticals <i>Half Moon Bay, CA</i> | ADHD (see also Alzheimer's disease) | Phase II (650) 560-1210 |
| SPD-465 | Shire <i>Wayne, PA</i> | ADHD | application submitted (434) 595-8800 |
| SPD-503 | Shire <i>Wayne, PA</i> | ADHD | application submitted (434) 595-8800 |

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 |
| AEE788 | Novartis Pharmaceuticals East Hanover, NJ | glioblastoma multiforme | Phase I (888) 669-6682 |
| aflibercept | Regeneron Pharmaceuticals Tarrytown, NY | glioma | Phase II (914) 345-7400 |
| AMG 102 | Amgen Thousand Oaks, CA | glioma | Phase II (805) 447-1000 |
| Avastin® bevacizumab | Genentech South San Francisco, CA | glioblastoma multiforme | Phase II (650) 225-1000 |
| banoxantrone | Novacea South San Francisco, CA | glioblastoma | Phase I (650) 228-1800 |
| belagenpuma- tucel-L (antisense therapy) | NovaRx San Diego, CA | brain cancer | Phase I (858) 552-8600 |
| BNP-1350 | BioNumerik Pharmaceuticals San Antonio, TX | primary brain cancer | Phase II (210) 614-1701 |
| cancer vaccine | ImmunoCellular Therapeutics Los Angeles, CA | glioblastoma | Phase I (310) 423-0845 |
| CC-8490 | Celgene Summit, NJ | glioblastoma | Phase II (908) 673-9000 |
| CDX-110 | Celldex Therapeutics Phillipsburg, NJ | glioblastoma | Phase II (908) 454-7120 |
| cilengitide (Orphan Drug) | EMD Serono Rockland, MA | glioblastoma | Phase II (800) 283-8088 |
| cintredekin besudotox (IL 13-PE38QQR) (Orphan Drug) | Neopharm Lake Forest, IL | glioblastoma multiforme (first recurrent) | Phase III (847) 295-8678 |
| | | glioblastoma multiforme (initial diagnosis) | Phase I (847) 295-8678 |
| contusugene ladenovec | Introgen Therapeutics Houston, TX | glioblastoma | Phase I (713) 797-9960 |
| Corlux™ mifepristone | Corcept Therapeutics Menlo Park, CA | meningioma (see also Alzheimer's disease) | Phase II (650) 327-3270 |
| Cotara® monoclonal antibody TNT-1 | Peregrine Pharmaceuticals Tustin, CA | glioblastoma multiforme | Phase I (714) 508-6000 |
| DCVax®-Brain brain cancer vaccine | Northwest Biotherapeutics Bethesda, MD Bothell, WA | glioblastoma | Phase II (425) 608-3000 |
| DTS-301 | Protherics Brentwood, TN | glioblastoma | Phase I (615) 327-1027 |

BRAIN TUMORS

| Product Name | Sponsor | Indication | Development Status |
|---|---|---|---|
| EM-1421 | Erimos Pharmaceuticals <i>Raleigh, NC</i> | glioma | Phase I (919) 821-5204 |
| EMD-273063 | EMD Serono <i>Rockland, MA</i> | neuroblastoma | Phase II (800) 283-8088 |
| EPO-906 (patupilone) | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | brain cancer | Phase II (888) 669-6682 |
| G207 | MediGene <i>San Diego, CA</i> | glioblastoma | Phase I (858) 586-2240 |
| gimatecan | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | malignant glioma | Phase I (888) 669-6682 |
| Gleevec® imatinib | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | glioblastoma multiforme | Phase II (888) 669-6682 |
| GliAtak™ cancer gene therapy | Advantagene <i>Boston, MA</i> | malignant glioma | Phase I (617) 916-5445 |
| Hycamtin™ topotecan | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | glioma | Phase II (888) 825-5249 |
| Iressa® gefitinib | AstraZeneca <i>Wilmington, DE</i> | glioblastoma | Phase II (800) 236-9933 |
| KRX-0401 (perifosine) | Keryx Biopharmaceuticals <i>Stamford, CT</i> | glioma | Phase II (604) 688-0199 |
| KRX-0402 (benzylguanine) | Keryx BioPharmaceuticals <i>Stamford, CT</i> | glioblastoma multiforme, glioma | Phase II (604) 688-0199 |
| lucanthone | Spectrum Pharmaceuticals <i>Irvine, CA</i> | recurrent malignant brain tumors | Phase II (949) 788-6700 |
| LY-317615 (enzastaurin) | Eli Lilly <i>Indianapolis, IN</i> | glioblastoma | Phase III (800) 545-5979 |
| MK-8669 (AP-23573) | ARIAD Pharmaceuticals <i>Cambridge, MA</i> Merck <i>Whitehouse Station, NJ</i> | glioblastoma | Phase I (617) 494-0400 (800) 672-6372 |
| motexafin gadolinium (MGd) | Pharmacyclics <i>Sunnyvale, CA</i> | lung cancer brain metastases (in combination with radiation) | application submitted (408) 774-0330 |
| | | glioma | Phase II (408) 774-0330 |
| | | glioblastoma | Phase I (408) 774-0330 |
| MPC-6827 | Myriad Pharmaceuticals <i>Salt Lake City, UT</i> | glioblastoma multiforme | Phase II (801) 584-3600 |
| neuradiab | Bradmer Pharmaceuticals <i>Toronto, ON</i> | glioblastoma multiforme | Phase II (416) 361-6058 |
| nimotuzumab | YM Biosciences <i>Wayne, PA</i> | inoperable, recurrent brain cancer | Phase II (610) 560-0600 |

BRAIN TUMORS

| Product Name | Sponsor | Indication | Development Status |
|--|---|---|--|
| Oncolar [®] octreotide | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | brain cancer | in clinical trials (888) 669-6682 |
| Panzem [®] NCD 2-methoxyestradiol | EntreMed <i>Rockville, MD</i> | glioblastoma | Phase II (240) 864-2601 |
| pazopanib | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | glioma | Phase I (888) 825-5249 |
| PRX-321 (IL-4 fusion toxin) | Protox Therapeutics <i>Vancouver, BC</i> | glioblastoma | Phase II (604) 688-0199 |
| Recentin [™] cediranib | AstraZeneca <i>Wilmington, DE</i> | recurrent glioblastoma | Phase III (800) 236-9933 |
| Reolysin [®] | Oncolytics Biotech <i>Calgary, AB</i> | glioma | Phase I (403) 670-7377 |
| Revlimid [®] lenalidomide | Celgene <i>Summit, NJ</i> | glioblastoma multiforme | Phase II (908) 673-9000 |
| RTA744 | Reata Pharmaceuticals <i>Irving, TX</i> | brain cancer (primary) | Phase II (972) 865-2219 |
| | | glioma | Phase I (972) 865-2219 |
| sagopilone | Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> | brain cancer, brain metastases | Phase II (888) 842-2937 |
| SBG | Biotec Pharmacon <i>Tromso, Norway</i> | neuroblastoma | Phase I |
| talampanel | IVAX Pharmaceuticals <i>Miami, FL</i> | glioma (see also epilepsy, Parkinson's disease) | Phase II (770) 970-7500 |
| Tarceva [®] erlotinib | Genentech <i>South San Francisco, CA</i> OSI Pharmaceuticals <i>Melville, NY</i> | glioblastoma multiforme | Phase II (650) 225-1000 (800) 572-1932 |
| Trisenox [®] arsenic trioxide | Cephalon <i>Frazer, PA</i> | recurrent malignant glioma | Phase I (610) 344-0200 |
| Tykerb [®] lapatinib | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | brain metastases | Phase III (888) 825-5249 |
| vatalanib | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | glioblastoma | Phase II (888) 669-6682 |
| vitespen (HSPPC-96) | Antigenics <i>New York, NY</i> | glioma | Phase II (866) 805-8994 |
| VNP-40101M | Vion Pharmaceuticals <i>New Haven, CT</i> | glioma | Phase II (203) 498-4210 |
| | | brain tumors (primary) | Phase I (203) 498-4210 |

BRAIN TUMORS

| Product Name | Sponsor | Indication | Development Status |
|--|---|-------------------------|--|
| VP101 | Access Pharmaceuticals <i>Dallas, TX</i> Virium Pharmaceuticals <i>Princeton, NJ</i> | glioblastoma | Phase II (214) 905-5100 (609) 951-2270 |
| Xerecept® corticotropin (Orphan Drug) | Celtic Pharma <i>Hamilton, Bermuda</i> | peritumoral brain edema | Phase III (441) 299-7440 |
| Xinlay™ atrasentan | Abbott Laboratories <i>Abbott Park, IL</i> | brain cancer | Phase II (847) 937-6100 |
| Zarnestra™ tipifarnib | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> | glioblastoma multiforme | Phase II (800) 817-5286 |
| Zolinza™ vorinostat | Merck <i>Whitehouse Station, NJ</i> | glioblastoma | Phase II (800) 672-6372 |

EPILEPSY

| Product Name | Sponsor | Indication | Development Status |
|--|---|---|---|
| carbamazepine intravenous | Ovation Pharmaceuticals <i>Deerfield, IL</i> | epilepsy | Phase III (847) 282-1000 |
| carisbamate (RWJ-333369) | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> | epilepsy | Phase III (800) 817-5286 |
| clobazam (Orphan Drug) | Ovation Pharmaceuticals <i>Deerfield, IL</i> | Lennox-Gastaut syndrome | Phase III (800) 455-1141 |
| Diastat® IN diazepam intranasal | Valeant Pharmaceuticals <i>Aliso Viejo, CA</i> | epilepsy | Phase I (800) 548-5100 |
| ganaxolone | Marinus Pharmaceuticals <i>Branford, CT</i> | infantile spasms, partial seizures | Phase II (203) 315-0566 |
| ICA-105665 | Icagen <i>Durham, NC</i> | epilepsy | Phase I (919) 941-5206 |
| JZP-4 | Jazz Pharmaceuticals <i>Palo Alto, CA</i> | epilepsy | Phase I (650) 496-3777 |
| JZP-8 (Orphan Drug) | Jazz Pharmaceuticals <i>Palo Alto, CA</i> | recurrent acute repetitive seizures | Phase II (650) 496-3777 |
| Keppra® XR levetiracetam (extended-release) | UCB <i>Smyrna, GA</i> | epilepsy | application submitted (770) 970-7500 |
| | | ----- epilepsy (monotherapy) | Phase III (770) 970-7500 |
| Lamictal® lamotrigine | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | absence seizures (pediatric) (see also pain) | Phase II (888) 825-5249 |

EPILEPSY

| Product Name | Sponsor | Indication | Development Status |
|--|--|--|---|
| Lamictal® XR lamotrigine (once daily) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | partial seizures | application submitted (888) 825-5249 |
| | | partial generalized tonic-clonic seizures | Phase III (888) 825-5249 |
| lorazepam intranasal | Intranasal Therapeutics <i>Lexington, KY</i> | seizures | Phase I (859) 252-5080 |
| Lyrica® pregabalin | Pfizer <i>New York, NY</i> | epilepsy (monotherapy) (see also pain, restless legs syndrome) | Phase III (860) 732-5156 |
| midazolam intranasal | Intranasal Therapeutics <i>Saddle Brook, NJ</i> | seizures | Phase I (201) 843-3308 |
| perampanel | Eisai <i>Ridgefield Park, NJ</i> | epilepsy (see also migraine, multiple sclerosis, pain, Parkinson's disease) | Phase II (888) 274-2378 |
| retigabine IR (immediate release) | Valeant Pharmaceuticals <i>Aliso Viejo, CA</i> | partial-onset seizures (see also pain) | Phase III (800) 548-5100 |
| retigabine SR (sustained-release) | Valeant Pharmaceuticals <i>Aliso Viejo, CA</i> | partial seizures | Phase I (800) 548-5100 |
| Rikelta® brivaracetam | UCB <i>Smyrna, GA</i> | epilepsy, Unverricht-Lundborg disease (myclonic seizures) | Phase III (770) 970-7500 |
| rufinamide | Eisai <i>Ridgefield Park, NJ</i> | epilepsy, Lennox-Gastaut syndrome | application submitted (888) 274-2378 |
| Sabril® vigabatrin (Orphan Drug) | Ovation Pharmaceuticals <i>Deerfield, IL</i> | infantile spasms, refractory complex partial seizures | in clinical trials (847) 282-1000 |
| SEP-0002093 | Sepracor <i>Marlborough, MA</i> | epilepsy | Phase III (508) 481-6700 |
| Stavzor™ valproic acid delayed-release softgel | Noven Pharmaceuticals <i>Miami, FL</i> | epilepsy (adjunctive therapy) (see also migraine) | application submitted (305) 253-5099 |
| T-2000 | Taro Pharmaceuticals USA <i>Hawthorne, NY</i> | epilepsy | Phase I (800) 544-1449 |
| talampanel | IVAX Pharmaceuticals <i>Miami, FL</i> | epilepsy (see also brain tumors, Parkinson's disease) | Phase II (305) 575-6000 |
| Vanquix™ diazepam | King Pharmaceuticals <i>Bristol, TN</i> | acute repetitive epileptic seizures (intramuscular) | Phase III (800) 776-3637 |
| Vimpat® lacosamide | UCB <i>Smyrna, GA</i> | epilepsy (adjunctive therapy) (see also migraine, pain) | application submitted (770) 970-7500 |
| | | epilepsy (monotherapy) | Phase III (770) 970-7500 |

HUNTINGTON'S DISEASE

| Product Name | Sponsor | Indication | Development Status |
|--|---|--|---|
| ACR16 (Orphan Drug) | Astellas Pharma US Deerfield, IL | Huntington's disease | Phase II (800) 727-7003 |
| creatine monohydrate (HD-02) | Avicena Palo Alto, CA | Huntington's disease (see also amyotrophic lateral sclerosis, muscular dystrophies, Parkinson's disease, other) | Phase II (415) 397-2880 |
| Dimebon TM dimebolin | Medivation San Francisco, CA | Huntington's disease | Phase II (415) 543-3470 |
| Strattera [®] atomoxetine | Eli Lilly Indianapolis, IN | Huntington's disease | Phase II (800) 545-5979 |
| tetrabenazine | Prestwick Pharmaceuticals Washington, DC | chorea associated with Huntington's disease | application submitted (202) 296-1400 |

MIGRAINE/HEADACHE

| Product Name | Sponsor | Indication | Development Status |
|--|---|--|---|
| 274150 (selective iNOS inhibitor) | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | migraine | Phase II (888) 825-5249 |
| AST-726 | Ariston Pharmaceuticals Framingham, MA | migraine prophylaxis | Phase I (508) 665-4260 |
| AZ-001 | Alexza Pharmaceuticals Mountain View, CA | acute migraine | Phase II (650) 944-7000 |
| AZ-104 (loxapine low-dose inhalation) | Alexza Pharmaceuticals Mountain View, CA Symphony Allegro Rockville, MD | migraine | Phase II (650) 944-7000 |
| Botox [®] botulinum toxin type A | Allergan Irvine, CA | chronic daily headache, migraine prophylaxis (see also pain, other) | Phase III (800) 433-8871 |
| butorphanol (nasal therapy) | Intranasal Therapeutics Lexington, KY | migraine (see also pain) | Phase III (859) 252-5080 |
| FHPC 01 | Sciele Pharma Atlanta, GA | migraine | Phase I (800) 461-3696 |
| Frova [®] frovatriptan (EN 3266) | Endo Pharmaceuticals Chadds Ford, PA Vernalis Pharmaceuticals Morristown, NJ | menstrual migraine prophylaxis | application submitted (610) 558-9800 |
| LY466195 | Eli Lilly Indianapolis, IN | migraine | Phase I (800) 545-5979 |
| MAP0004 | MAP Pharmaceuticals Mountain View, CA | migraine | Phase II (650) 386-3100 |
| Maxalt [®] rizatriptan | Merck Whitehouse Station, NJ | menstrual migraine | Phase III (800) 672-6372 |

MIGRAINE/HEADACHE

| Product Name | Sponsor | Indication | Development Status |
|---|---|---|---|
| mGluR3 antagonist | Eli Lilly <i>Indianapolis, IN</i> | migraine | Phase II (800) 545- 5979 |
| MK-0974 | Merck <i>Whitehouse Station, NJ</i> | migraine | Phase III (800) 672-6372 |
| Neurontin [®] gabapentin | Pfizer <i>New York, NY</i> | migraine | Phase II (860) 732-5156 |
| NGX426 | TorreyPines Therapeutics <i>La Jolla, CA</i> | migraine (see also pain) | Phase I (858) 623-5665 |
| NP-101 | NuPathe <i>Conshohocken, PA</i> | migraine | Phase I (484) 567-0130 |
| olcegepant (BIBN-4096) | Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> | migraine | Phase II (203) 798-9988 |
| perampanel | Eisai <i>Ridgefield Park, NJ</i> | migraine prophylaxis (see also epilepsy, multiple sclerosis, pain, Parkinson's disease) | Phase II (888) 274-2378 |
| PNU 142633F | Pfizer <i>New York, NY</i> | cluster headache, classic and common migraine | Phase II (860) 732-5156 |
| PRO-513 | ProEthic Pharmaceuticals <i>Montgomery, AL</i> | migraine | application submitted (334) 288-1288 |
| Relpax [®] eletriptan | Pfizer <i>New York, NY</i> | menstrual migraine | in clinical trials (860) 732-5156 |
| Stavzor [™] valproic acid (delayed-release softgel) | Noven Pharmaceuticals <i>Miami, FL</i> | migraine prophylaxis (see also epilepsy) | application submitted (305) 253-5099 |
| sumatriptan Intraject [®] (needle-free) | Zogenix <i>San Diego, CA</i> | migraine | application submitted (858) 259-1165 |
| sumatriptan oral spray | NovaDel Pharma <i>Fleming, NJ</i> | migraine | Phase I (908) 782-3431 |
| tezampanel (NGX424) | TorreyPines Therapeutics <i>La Jolla, CA</i> | migraine (see also pain) | Phase II (858) 623-5665 |
| tonabersat | Minster Pharmaceuticals <i>Essex, United Kingdom</i> | migraine | Phase II |
| Trexima [™] sumatriptan succinate/ naproxen sodium (fixed-dose combination) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> POZEN <i>Chapel Hill, NC</i> | migraine (acute treatment) | application submitted (888) 825-5249 (919) 913-1030 |
| Vimpat [®] lacosamide | UCB <i>Smyrna, GA</i> | migraine prophylaxis (see also epilepsy, pain) | Phase III (770) 970-7500 |
| Zomig [®] zolmitriptan | Meda Pharmaceuticals <i>Somerset, NJ</i> | cluster headache | Phase II (732) 564-2200 |

MULTIPLE SCLEROSIS

| Product Name | Sponsor | Indication | Development Status |
|---------------------------------|--|--|---|
| atacept (TACI-Ig) | EMD Serono Rockland, MA ZymoGenetics Seattle, WA | multiple sclerosis (see also systemic lupus erythematosus) | Phase II (800) 283-8088 (800) 775-6686 |
| AZD5904 | AstraZeneca Wilmington, DE | multiple sclerosis | Phase I (800) 236-9933 |
| BG-12 (dimethyl fumarate) | Biogen Idec Cambridge, MA | multiple sclerosis (relapsing forms) | Phase III (617) 679-2000 |
| BHT-3009 | Bayhill Therapeutics Palo Alto, CA | multiple sclerosis | Phase II (650) 320-2800 |
| Campath® alemtuzumab | Bayer HealthCare Pharmaceuticals Wayne, PA Genzyme Cambridge, MA | multiple sclerosis | Phase III (617) 252-7000 (888) 842-2937 |
| CCX-915 | ChemoCentryx Mountain View, CA | multiple sclerosis | Phase I (650) 210-2900 |
| CDP323 | Biogen Idec Cambridge, MA UCB Smyrna, GA | multiple sclerosis (relapsing forms) | Phase II (617) 679-2000 (770) 970-7500 |
| fampridine-SR | Acorda Therapeutics Hawthorne, NY | multiple sclerosis | Phase III (914) 347-4300 |
| fingolimod (FTY720) | Novartis Pharmaceuticals East Hanover, NJ | multiple sclerosis | Phase III (888) 669-6682 |
| firategrast (683699) | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | multiple sclerosis | Phase II (888) 825-5249 |
| fludarabine (oral) | Xanthus Pharmaceuticals Cambridge, MA | multiple sclerosis | Phase II (617) 225-0522 |
| immune globulin intravenous | Talecris Biotherapeutics Rsch. Triangle Park, NC | multiple sclerosis | Phase III (919) 316-6300 |
| INCB-8696 | Incyte Wilmington, DE Pfizer New York, NY | multiple sclerosis | Phase I (302) 498-6700 (860) 732-5156 |
| interferon-alpha-n3 | Hemispherx Biopharma Philadelphia, PA | multiple sclerosis | Phase II (215) 988-0080 |
| JNK inhibitor | EMD Serono Rockland, MA | multiple sclerosis | Phase I (800) 283-8088 |
| laquinimod | Teva Pharmaceuticals North America North Wales, PA | relapsing-remitting multiple sclerosis | Phase II/III (215) 591-3000 |
| Leukine® sargramostim | Bayer HealthCare Pharmaceuticals Wayne, NJ | multiple sclerosis | Phase I (888) 842-2937 |

MULTIPLE SCLEROSIS

| Product Name | Sponsor | Indication | Development Status |
|--|--|---|---|
| MBP-8298 | BioMS Medical Edmonton, AB Eli Lilly Indianapolis, IN | multiple sclerosis | Phase III (800) 545-5979 |
| MK-0812 | Merck Whitehouse Station, NJ | multiple sclerosis | Phase II (800) 672-6372 |
| MLN1202 | Millennium Pharmaceuticals Cambridge, MA | multiple sclerosis | Phase II (800) 390-5663 |
| MLN3897 | Millennium Pharmaceuticals Cambridge, MA | multiple sclerosis | Phase I (800) 390-5663 |
| MM-093 | Merrimack Pharmaceuticals Cambridge, MA | multiple sclerosis (see also other) | Phase I (617) 441-1000 |
| Mylinax [®] oral cladribine | IVAX Pharmaceuticals Miami, FL EMD Serono Rockford, MA | multiple sclerosis | Phase III (305) 575-6000 (800) 283-8088 |
| nerispiridine (HP184) | sanofi-aventis Bridgewater, NJ | multiple sclerosis | Phase II (800) 633-1610 |
| NeuroVax [™] (IR208 vaccine) | Orchestra Therapeutics Carlsbad, CA | multiple sclerosis | Phase II (760) 431-7080 |
| ocrelizumab (2nd generation anti-CD20) | Biogen Idec Cambridge, MA Genentech South San Francisco, CA | relapsing-remitting multiple sclerosis (see also systemic lupus erythematosus) | Phase II (617) 679-2000 (650) 225-1000 |
| PEG-Intron [®] peginterferon alfa-2b | Schering-Plough Kenilworth, NJ | multiple sclerosis | Phase II (908) 298-4000 |
| perampanel | Eisai Ridgefield Park, NJ | multiple sclerosis (see also epilepsy, migraine, pain, Parkinson's disease) | Phase II (888) 274-2378 |
| PI-2301 | Peptimmune Cambridge, MA | multiple sclerosis | Phase I (617) 715-8000 |
| pioglitazone | Takeda Pharmaceuticals North America Deerfield, IL | relapsing-remitting multiple sclerosis | Phase I (224) 554-6500 |
| R411 (valategrast) | Roche Nutley, NJ | multiple sclerosis | Phase I (973) 235-5000 |
| R1295 | Roche Nutley, NJ | multiple sclerosis | Phase I (973) 235-5000 |
| Rebif [®] interferon beta-1a (new formulation) | EMD Serono Rockland, MA Pfizer New York, NY | relapsing-remitting multiple sclerosis | application submitted (800) 283-8088 (860) 732-5156 |

MULTIPLE SCLEROSIS

| Product Name | Sponsor | Indication | Development Status |
|---|--|---|---|
| Rituxan [®] rituximab | Biogen Idec <i>Cambridge, MA</i> Genentech <i>South San Francisco, CA</i> | primary progressive multiple sclerosis (see also systemic lupus erythematosus) | Phase III (617) 679-2000 (650) 225-1000 |
| | | relapsing-remitting multiple sclerosis | Phase II (617) 679-2000 (650) 225-1000 |
| RPI-78M | ReceptoPharm <i>Plantation, FL</i> | multiple sclerosis | Phase I (954) 321-8988 |
| Sativex [®] dronabinol/ cannabidiol | GW Pharmaceuticals <i>Wiltshire, United Kingdom</i> Otsuka America Pharmaceutical <i>Rockville, MD</i> | spasticity in multiple sclerosis (see also pain) | Phase II (800) 562-3974 |
| Tauferon [™] interferon-tau | Pepgen <i>Alameda, CA</i> | multiple sclerosis | Phase II (510) 473-0010 |
| TBC-4746 | Encysive Pharmaceuticals <i>Houston, TX</i> Schering-Plough <i>Kenilworth, NJ</i> | multiple sclerosis | Phase I (713) 796-8822 (908) 298-4000 |
| teplizumab | MacroGenics <i>Rockville, MD</i> Eli Lilly <i>Indianapolis, IN</i> | multiple sclerosis | Phase I (301) 251-5172 (800) 545-5979 |
| teriflunomide (HMR1726) | sanofi-aventis <i>Bridgewater, NJ</i> | multiple sclerosis (monotherapy) | Phase III (800) 633-1610 |
| | | multiple sclerosis (adjunct therapy) | Phase II (800) 633-1610 |
| Torisel [™] temsirolimus | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | multiple sclerosis | Phase II (800) 934-5556 |
| Tovaxin [®] autologous T-cell vaccine | Opexa Therapeutics <i>The Woodlands, TX</i> | multiple sclerosis | Phase I/II (281) 272-9331 |
| tranilast | Nuon Therapeutics <i>San Mateo, CA</i> | multiple sclerosis | in clinical trials (650) 208-3478 |
| Trimesta [™] estriol | Pipex Pharmaceuticals <i>Ann Arbor, MI</i> | multiple sclerosis | Phase II (734) 332-7800 |
| ustekinumab (CNTO 1275) | Centocor <i>Horsham, PA</i> | multiple sclerosis | Phase II (610) 651-6000 |
| Zenapax [®] daclizumab | Biogen Idec <i>Cambridge, MA</i> PDL BioPharma <i>Redwood City, CA</i> | multiple sclerosis (relapsing forms) | Phase II (617) 679-2000 (650) 454-1000 |

MUSCULAR DYSTROPHIES

| Product Name | Sponsor | Indication | Development Status |
|--|--|--|---|
| AVI-4658 | AVI BioPharma <i>Portland, OR</i> Ercole Biotech <i>Rsch. Triangle Park, NC</i> | Duchenne muscular dystrophy | Phase I (503) 227-0554 (919) 647-4452 |
| Biostrophin™ muscular dystrophy gene therapy | Asklêpios BioPharmaceuticals <i>Chapel Hill, NC</i> | Duchenne muscular dystrophy | in clinical trials (919) 933-4990 |
| creatine monohydrate (DMD-02) | Avicena <i>Palo Alto, CA</i> | Duchenne muscular dystrophy (see also amyotrophic lateral sclerosis, Huntington's disease, Parkinson's disease, other) | Phase I (415) 397-1880 |
| IPLEX™ mecasermin rinfabate | Insméd <i>Richmond, VA</i> | myotonic muscular dystrophy | Phase III (804) 565-3000 |
| omigapil | Novartis Pharmaceuticals <i>East Hanover, NJ</i> Santhera Pharmaceuticals <i>Liestal, Switzerland</i> | congenital muscular dystrophy | Phase II (888) 669-6682 |
| PTC124 | PTC Therapeutics <i>South Plainfield, NJ</i> | muscular dystrophy | Phase II (908) 222-7000 |
| stamulumab (MYO-029) | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | Becker muscular dystrophy, facioscapulohumeral muscular dystrophy, limb-girdle muscular dystrophy | Phase II (800) 934-5556 |

PAIN

| Product Name | Sponsor | Indication | Development Status |
|---|--|-----------------------------------|---|
| 406381 (dual-acting COX-2 inhibitor) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | acute and chronic pain | Phase III (888) 825-5249 |
| 681323 | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | neuropathic pain | Phase II (888) 825-5249 |
| 705498 (vanilloid 1 antagonist) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | pain ----- dental pain | Phase II (888) 825-5249 Phase I (888) 825-5249 |
| 842166 (non-cannabinoid CB2 agonist) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | dental pain, musculoskeletal pain | Phase II (888) 825-5249 |

PAIN

| Product Name | Sponsor | Indication | Development Status |
|---|--|--|--|
| 1838262 (XP13512) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> XenoPort <i>Santa Clara, CA</i> | neuropathic pain, post-herpetic neuralgia (see also restless legs syndrome) | Phase II (888) 825-5249 (408) 616-7200 |
| ABT-894 | Abbott Laboratories <i>Abbott Park, IL</i> | diabetic neuropathies (see also attention-deficit hyperactivity disorder) | Phase II (847) 937-6100 |
| ABT-963 | Abbott Laboratories <i>Abbott Park, IL</i> | pain | Phase I (847) 937-6100 |
| Acurox™ oxycodone | Acura Pharmaceuticals <i>Palantine, IL</i> | pain | Phase III (847) 705-7709 |
| ADL 5859 | Adolor <i>Exton, PA</i> Pfizer <i>New York, NY</i> | dental pain, diabetic neuropathies, inflammatory pain | Phase II (484) 595-1500 (860) 732-5156 |
| AGN201781 (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 |
| AGN203818 | ACADIA Pharmaceuticals <i>San Diego, CA</i> Allergan <i>Irvine, CA</i> | diabetic neuropathies, pain | Phase II (858) 558-2871 (714) 246-4500 |
| ALGRX 4975 | Anesiva <i>South San Francisco, CA</i> | neuropathic pain, post-operative pain | Phase II (650) 624-9600 |
| alvimopan/opioid analgesic combination | Adolor <i>Englewood Cliffs, NJ</i> | pain | Phase II (484) 595-1500 |
| amelior | Cumberland Pharmaceuticals <i>Nashville, TN</i> | post-operative pain | Phase III (666) 423-7259 |
| AMG 379 | Amgen <i>Thousand Oaks, CA</i> | pain | Phase I (805) 447-1000 |
| AMG 403 | Amgen <i>Thousand Oaks, CA</i> | pain | Phase I (805) 447-1000 |
| ARC-4558 | Arcion Therapeutics <i>Baltimore, MD</i> | diabetic neuropathies | Phase II (301) 325-3718 |
| Arcoxia™ etoricoxib (MK-663) | Merck <i>Whitehouse Station, NJ</i> | back pain, dental pain | Phase III (800) 672-6372 |
| ARRY-797 | Array BioPharma <i>Boulder, CO</i> | inflammatory pain | Phase II (877) 633-2436 |
| AT-3022 | Altea Therapeutics <i>Atlanta, GA</i> | pain | Phase I (404) 835-6310 |

PAIN

| Product Name | Sponsor | Indication | Development Status |
|--|---|--|---|
| AV411 | Avigen <i>Alameda, CA</i> | neuropathic pain | Phase I (510) 748-7150 |
| AVP923 | Avanir Pharmaceuticals <i>San Diego, CA</i> | diabetic neuropathies (see also other) | Phase III (858) 622-5200 |
| AZD1386 | AstraZeneca <i>Wilmington, DE</i> | chronic nociceptive pain | Phase I (800) 236-9933 |
| AZD1940 | AstraZeneca <i>Wilmington, DE</i> | neuropathic pain, nociceptive pain | Phase I (800) 236-9933 |
| AZD2066 | AstraZeneca <i>Wilmington, DE</i> | chronic nociceptive pain | Phase I (800) 236-9933 |
| Bema™ fentanyl transmucosal | Biodelivery Sciences <i>Raleigh, NC</i> Meda Pharmaceuticals <i>Somerset, NJ</i> | cancer pain | application submitted (919) 582-9050 |
| bicifadine | XTL Biopharmaceuticals <i>Valley Cottage, NY</i> | diabetic neuropathies | Phase II (845) 267-0707 |
| Botox® botulinum toxin type A | Allergan <i>Irvine, CA</i> | back pain (see also migraine, other) | Phase III (800) 433-8871 |
| bupivacaine | Pacira Pharmaceuticals <i>San Diego, CA</i> | post-operative pain | Phase II (858) 625-2424 |
| buprenorphine transdermal | Mundipharma <i>Cambridge, United Kingdom</i> | pain | Phase III |
| buprenorphine transmucosal | Biodelivery Sciences <i>Raleigh, NC</i> | pain | Phase I (919) 582-9050 |
| butorphanol (nasal therapy) | Intranasal Therapeutics <i>Lexington, KY</i> | pain (see also migraine) | Phase III (859) 252-5080 |
| C-6740 | Merck <i>Whitehouse Station, NJ</i> | pain | Phase I (800) 672-6372 |
| C-8928 | Merck <i>Whitehouse Station, NJ</i> | pain | Phase I (800) 672-6372 |
| CDS PM101 | pSivida <i>Watertown, MA</i> | post-operative pain | Phase I (617) 926-5000 |
| CE 224535 | Pfizer <i>New York, NY</i> | inflammatory pain | Phase II (860) 732-5156 |
| Cellegesic™ 0.4% nitroglycerin ointment | ProStrakan <i>Galashiels, United Kingdom</i> | pain reduction for chronic anal fissures | application submitted www.prostrakan.com |
| Cesamet® nabilone | Valeant Pharmaceuticals <i>Aliso Viejo, CA</i> | neuropathic pain | Phase II (800) 548-5100 |
| CGX-1160 | Cognetix <i>Salt Lake City, UT</i> | chronic intractable pain caused by spinal cord injury | Phase I (801) 581-0400 |
| CJ 15161 | Pfizer <i>New York, NY</i> | back pain, cancer pain | Phase II (860) 732-5156 |

PAIN

| Product Name | Sponsor | Indication | Development Status |
|--|---|---|---|
| COL-003 | Collegium Pharmaceuticals <i>Cumberland, RI</i> | pain | Phase I (401) 762-2000 |
| CollaRx® bupivacaine implant | Innocoll <i>Ashburn, VA</i> | post-operative pain | Phase II |
| CR665 | ALZA <i>Mountain View, CA</i> Cara Therapeutics <i>Shelton, CT</i> | post-operative pain | Phase II (203) 567-1500 |
| CS-502 | Daiichi Sankyo <i>Parsippany, NJ</i> | pain | Phase II (973) 359-2600 |
| CS-706 | Daiichi Sankyo <i>Parsippany, NJ</i> | pain | Phase II (973) 359-2600 |
| DD5 | Cephalon <i>Frazer, PA</i> | pain | Phase I (610) 344-0200 |
| DPI-125 | Mount Cook Biosciences <i>New York, NY</i> | pain | Phase I |
| duloxetine | Eli Lilly <i>Indianapolis, IN</i> | fibromyalgia syndrome | application submitted (800) 545-5979 |
| | | back pain, musculoskeletal pain | Phase III (800) 545-5979 |
| Dyloject™ injectable diclofenac | Javelin Pharmaceuticals <i>Cambridge, MA</i> | post-operative pain | Phase III (617) 349-4500 |
| Dynastat® parecoxib | Pfizer <i>New York, NY</i> | pain management | application submitted (860) 732-5156 |
| Eladur™ bupivacaine transdermal | DURECT <i>Cupertino, CA</i> ProEthic Pharmaceuticals <i>Montgomery, AL</i> | postherpetic neuralgia | Phase II (408) 777-1417 (334) 288-1288 |
| | | pain | Phase I (408) 777-1417 (334) 288-1288 |
| EN 3269 (topical ketoprofen patch) | Endo Pharmaceuticals <i>Chadds Ford, PA</i> ProEthic Pharmaceuticals <i>Montgomery, AL</i> | localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains | Phase III (610) 558-9800 (334) 288-1288 |
| EN 3270 (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 |
| EN 3294 (inhaled fentanyl) | Alexza Pharmaceuticals <i>Palo Alto, CA</i> Endo Pharmaceuticals <i>Chadds Ford, PA</i> | acute pain | Phase I (650) 944-7000 (610) 558-9800 |

PAIN

| Product Name | Sponsor | Indication | Development Status |
|--|--|---|---|
| fentanyl transdermal patch | Lavipharm <i>East Windsor, NJ</i> | cancer pain | Phase III (609) 448-3001 |
| Fentora [®] fentanyl effervescent buccal tablet | Cephalon <i>West Chester, PA</i> | breakthrough pain associated with chronic pain | application submitted (610) 344-0200 |
| Gabapentin GR [™] gabapentin extended-release | Depomed <i>Menlo Park, CA</i> | post-herpetic neuralgia | Phase III (650) 462-5900 |
| | | ----- diabetic neuropathies | Phase II (650) 462-5900 |
| Gabitril [®] tiagabine | Cephalon <i>Frazer, PA</i> | neuropathic pain (see also sleep disorders) | Phase II (610) 344-0200 |
| glial cell modulator | Solace Pharmaceuticals <i>Boston, MA</i> | pain | Phase I www.solacepharma.com |
| hydromorphone controlled-release | Neuromed Pharmaceuticals <i>Philadelphia, PA</i> | pain | Phase III (484) 533-6900 |
| hydromorphone (nasal therapy) | Intranasal Therapeutics <i>Lexington, KY</i> | acute and moderate to severe pain | Phase II (859) 252-5080 |
| hydromorphone transdermal | Altea Therapeutics <i>Tucker, GA</i> | acute and chronic pain | Phase II (678) 495-3100 |
| HZT-501 (ibuprofen/ famotidine) | Horizon Therapeutics <i>Palo Alto, CA</i> | pain | Phase III (650) 324-8700 |
| IDEA-033 (ketoprofen transdermal) | Alpharma <i>Bridgewater, NJ</i> | pain | Phase III (866) 322-2525 |
| indantadol | Vernalis Pharmaceuticals <i>Morristown, NJ</i> | neuropathic pain | Phase II (888) 376-2547 |
| intranasal morphine | Nastech Pharmaceutical <i>Bothell, WA</i> | breakthrough cancer pain, dental pain | Phase II (425) 908-3600 |
| IV-adenosine | Xsira Pharmaceuticals <i>Morrisville, NC</i> | post-operative pain | Phase II (919) 248-8000 |
| IV APAP | Cadence Pharmaceuticals <i>San Diego, CA</i> | acute pain | Phase III (858) 426-1400 |
| KD-7040 | Kalypsys <i>San Diego, CA</i> | neuropathic pain | Phase II (858) 754-3300 |
| KDS 2000 | Kadmus Pharmaceuticals <i>Irvine, CA</i> | postherpetic neuralgia | Phase II (949) 725-3700 |
| KRN5500 | DARA Biosciences <i>Raleigh, NC</i> | neuropathic pain | Phase II (919) 872-5578 |
| Lamictal [®] lamotrigine | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | neuropathic pain (see also epilepsy) | Phase III (888) 825-5249 |

PAIN

| Product Name | Sponsor | Indication | Development Status |
|--|---|---|--|
| lidocaine (vaginal) | Columbia Laboratories <i>Livingston, NJ</i> | gynecologic pain | Phase II (866) 566-5636 |
| Lidoderm® lidocaine patch 5% (EN 3260) | Endo Pharmaceuticals <i>Chadds Ford, PA</i> | chronic pain | Phase II (610) 558-9800 |
| LidoPAIN® BP lidocaine transdermal patch | Endo Pharmaceuticals <i>Chadds Ford, PA</i> EpiCept <i>Englewood Cliffs, NJ</i> | low back pain | Phase II (610) 558-9800 (201) 894-8980 |
| LidoPAIN® SP lidocaine transdermal patch | EpiCept <i>Englewood Cliffs, NJ</i> | surgical incision pain | Phase II (201) 894-8980 |
| lidorestat (ALN 101) | Alinea Pharmaceuticals <i>Cambridge, MA</i> | diabetic neuropathies | Phase II (617) 914-0123 |
| lornoxicam | POZEN <i>Chapel Hill, NC</i> | post-operative pain | Phase I/II (919) 913-1030 |
| LPCN-1029 | Lipocine <i>Salt Lake City, UT</i> | pain | Phase I (801) 994-7383 |
| Lyrica® pregabalin | Pfizer <i>New York, NY</i> | pain, post-operative pain (see also epilepsy, restless legs syndrome) | Phase III (860) 732-5156 |
| M6G | CeNes Pharmaceuticals <i>Cambridge, United Kingdom</i> | pain | Phase I |
| MCC-257 | Mitsubishi Tanabe Pharma America <i>Warren, NJ</i> | diabetic neuropathies | Phase II (908) 607-1950 |
| mepivacaine controlled-release (APF-112) | A.P. Pharma <i>Redwood City, CA</i> | post-operative pain | Phase II (650) 366-2626 |
| MGX-001 | Victory Pharma <i>San Diego, CA</i> | pain | Phase II (858) 720-4500 |
| milnacipran | Cypress Biosciences <i>San Diego, CA</i> Forest Laboratories <i>New York, NY</i> | fibromyalgia syndrome | application submitted (858) 452-2323 |
| MK-0677 (ibutamoren) | Merck <i>Whitehouse Station, NJ</i> | fibromyalgia syndrome | Phase II (800) 672-6372 |
| MK-0686 | Merck <i>Whitehouse Station, NJ</i> | postherpetic neuralgia | Phase II (800) 672-6372 |
| MK-0703 | Merck <i>Whitehouse Station, NJ</i> | pain | Phase II (800) 672-6372 |
| MK-0759 | Merck <i>Whitehouse Station, NJ</i> | postherpetic neuralgia | Phase II (800) 672-6372 |

PAIN

| Product Name | Sponsor | Indication | Development Status |
|--|---|---|--|
| MK-2295 | Merck <i>Whitehouse Station, NJ</i> Neurogen <i>Branford, CT</i> | pain | Phase II (800) 672-6372 (203) 488-8201 |
| morphine extended-release/ naltrexone combination | Alpharma <i>Bridgewater, NJ</i> | pain | Phase III (866) 322-2525 |
| morphine oral | Generex Biotechnology <i>Toronto, ON</i> | pain | Phase I (416) 364-2551 |
| Myocloc [®] botulinum toxin B | Solstice Neurosciences <i>South San Francisco, CA</i> | pain | in clinical trials (650) 243-4400 |
| Namenda [®] memantine HCl | Forest Laboratories <i>New York, NY</i> | neuropathic pain | Phase III (800) 947-5227 |
| Nasalfent [®] fentanyl intranasal | Archimedes Pharma <i>Reading, United Kingdom</i> | cancer pain | Phase III |
| neramexane | Forest Laboratories <i>New York, NY</i> | chronic pain (see also Alzheimer's disease) | Phase II (800) 947-5227 |
| NGX426 | TorreyPines Therapeutics <i>La Jolla, CA</i> | neuropathic pain (see also migraine) | Phase I (858) 623-5665 |
| NGX-4010 | NeurogesX <i>San Carlos, CA</i> | pain related to HIV-associated neuropathy, postherpetic neuralgia | Phase III (650) 508-2116 |
| NP-1 (amitriptyline/ ketamine) | EpiCept <i>Englewood Cliffs, NJ</i> | neuropathic pain due to diabetes, chemotherapy or shingles | Phase III (201) 894-8980 |
| NP-2 (ketamine butamben topical) | Epicept <i>Tarrytown, NY</i> | neuropathic pain | Phase I (914) 606-3500 |
| NRP290 | Shire <i>Wayne, PA</i> | pain | Phase I (484) 595-8800 |
| opioid analgesic | Zogenix <i>San Diego, CA</i> | pain | Phase II (858) 259-1165 |
| OxyNal [™] oxycodone/ naltrexone | Elite Pharmaceuticals <i>Northvale, NJ</i> | pain | Phase II (201) 750-2646 |
| OxyQD [™] oxycodone (once-daily) | Elite Pharmaceuticals <i>Northvale, NJ</i> | pain | Phase I (201) 750-2646 |
| Oxytrex [™] oxycodone and low-dose naltrexone | Pain Therapeutics <i>San Mateo, CA</i> | musculoskeletal pain | Phase III (650) 624-8200 |
| | | ----- cancer pain | Phase II (650) 624-8200 |
| pamidronic acid | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | cancer pain | Phase III (888) 669-6682 |

PAIN

| Product Name | Sponsor | Indication | Development Status |
|--|---|--|---|
| perampanel | Eisai <i>Ridgefield Park, NJ</i> | neuropathic pain (see also epilepsy, migraine, multiple sclerosis, Parkinson's disease) | Phase II (888) 274-2378 |
| PF-592379 | Pfizer <i>New York, NY</i> | pain | Phase II (860) 732-5156 |
| PF-738502 | Pfizer <i>New York, NY</i> | fibromyalgia syndrome | Phase I (860) 732-5156 |
| PF-3557156 | Pfizer <i>New York, NY</i> | pain | Phase I (860) 732-5156 |
| PF-4136309 | Pfizer <i>New York, NY</i> | pain | Phase I (860) 732-5156 |
| PF-4383119 | Pfizer <i>New York, NY</i> | back pain, cancer pain, musculoskeletal pain, neuralgia | Phase II (860) 732-5156 |
| PF-4480682 | Pfizer <i>New York, NY</i> | neuropathic pain | Phase I (860) 732-5156 |
| PMI-150 (intranasal ketamine) | Javelin Pharmaceuticals <i>Cambridge, MA</i> | cancer pain | Phase III (617) 349-4500 |
| | | ----- acute pain | Phase II (617) 349-4500 |
| PN-400 (esomeprazole/ naproxen) | AstraZeneca <i>Wilmington, DE</i> POZEN <i>Chapel Hill, NC</i> | pain | Phase III (800) 236-9933 |
| Posidur™ bupivacaine controlled-release | DURECT <i>Cupertino, CA</i> | post-operative pain | Phase II (408) 777-1417 |
| Prexige® lumiracoxib | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | pain | Phase III (888) 669-6682 |
| Pristiq™ desvenlafaxine | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | fibromyalgia, neuropathic pain | Phase III (800) 934-5556 |
| PRO-571 (diclofenac rapid-release) | ProEthic Pharmaceuticals <i>Montgomery, AL</i> | pain | Phase I (334) 288-1288 |
| Prosaptide™ | Savient Pharmaceuticals <i>East Brunswick, NJ</i> | neuropathic pain | Phase II (732) 418-9300 |
| ProSorb-D® diclofenac | Xanodyne Pharmaceuticals <i>Newport, KY</i> | pain | Phase III (877) 926-6396 |
| PTI-202 | King Pharmaceuticals <i>Bristol, TN</i> Pain Therapeutics <i>San Mateo, CA</i> | pain | Phase I (800) 776-3637 (650) 624-8200 |
| PW4142 | Penwest Pharmaceuticals <i>Danbury, CT</i> | pain | Phase II (203) 796-3700 |

PAIN

| Product Name | Sponsor | Indication | Development Status |
|--|---|--|---|
| Q8003IR (immediate-release) | QRxPharma <i>North Sydney, Australia</i> | pain | Phase III |
| QR-333 | Quigley Pharma <i>Doylestown, PA</i> | diabetic neuropathies | Phase II (267) 880-1100 |
| QSC-001 | Questcor Pharmaceuticals <i>Union City, PA</i> | pain | Phase I (510) 400-0700 |
| R1646 | Roche <i>Nutley, NJ</i> | pain | Phase I (973) 235-5000 |
| R331333 (immediate-release) | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> | pain, post-operative pain | Phase III (800) 817-5286 |
| R331333 PR (controlled-release) | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> | back pain, diabetic neuropathies, pain | Phase III (800) 817-5286 |
| Rapinyl™ fentanyl (sublingual) (EN 3267) | Endo Pharmaceuticals <i>Chadds Ford, PA</i> Orexo <i>Uppsala, Sweden</i> | breakthrough cancer pain | Phase III (610) 558-9800 |
| Reloxin® botulinum toxin A | Ipsen <i>Milford, MA</i> | myofascial pain (see also other) | Phase II (508) 478-8900 |
| Remoxy™ oxycodone | DURECT <i>Cupertino, CA</i> King Pharmaceuticals <i>Bristol, TN</i> Pain Therapeutics <i>San Mateo, CA</i> | pain | Phase III (800) 776-3637 (650) 624-8200 |
| retigabine IR (immediate release) | Valeant Pharmaceuticals <i>Aliso Viejo, CA</i> | postherpetic neuralgia (see also epilepsy) | Phase II (800) 548-5100 |
| RGH-896 (radiprodil) | Forest Laboratories <i>New York, NY</i> | pain | Phase I (800) 947-5227 |
| ROX-888 | ROXRO Pharma <i>Menlo Park, CA</i> | post-operative pain | Phase III (650) 322-4554 |
| RPI-70 | ReceptoPharm <i>Plantation, FL</i> | pain | Phase I (954) 321-8988 |
| Rylomine™ intranasal morphine | Javelin Pharmaceuticals <i>Cambridge, MA</i> | post-operative pain | Phase III (617) 349-4500 |
| SAB-378 | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | pain | Phase II (888) 669-6682 |
| Sativex® dronabinol/ cannabidiol | GW Pharmaceuticals <i>Wiltshire, United Kingdom</i> Otsuka America Pharmaceutical <i>Rockville, MD</i> | cancer pain (see also multiple sclerosis) ----- neuropathic pain, neuropathic pain in multiple sclerosis | Phase III (800) 562-3974 Phase II (800) 562-3974 |

PAIN

| Product Name | Sponsor | Indication | Development Status |
|---|---|--|---|
| SB-509 | Sangamo BioSciences <i>Richmond, CA</i> | diabetic neuropathies | Phase II (510) 970-6000 |
| SCIO-469 | Scios <i>Mountain View, CA</i> | dental pain | Phase II (650) 564-5000 |
| SCP-1 | St. Charles Pharmaceuticals <i>New Orleans, LA</i> | pain | Phase I (775) 626-0534 |
| selective norepinephrine reuptake inhibitor | Neurocrine Biosciences <i>San Diego, CA</i> | neuropathic pain | Phase I (858) 617-7600 |
| SRSS-001 | Sosei R&D <i>Tokyo, Japan</i> | cancer pain | Phase I |
| SSR150106 | sanofi-aventis <i>Bridgewater, NJ</i> | pain | Phase II (800) 633-1610 |
| SSR180575 | sanofi-aventis <i>Bridgewater, NJ</i> | diabetic polyneuropathies | Phase II (800) 633-1610 |
| SYN-116 | Roche <i>Nutley, NJ</i> Synosia Therapeutics <i>South San Francisco, CA</i> | pain | Phase I (973) 235-5000 (650) 244-4850 |
| T-62 | King Pharmaceuticals <i>Bristol, TN</i> | postherpetic neuralgia | Phase II (800) 776-3637 |
| TAK-428 | Takeda Pharmaceuticals North America <i>Deerfield, IL</i> | diabetic neuropathies | Phase II (224) 554-6500 |
| TAK-583 | Takeda Pharmaceuticals North America <i>Deerfield, IL</i> | diabetic neuropathies, postherpetic neuralgia | Phase II (224) 554-6500 |
| TamoGel™ afimoxifene | ASCEND Therapeutics <i>Herndon, VA</i> | breast pain | Phase II (703) 471-4744 |
| TC-2696 | Targacept <i>Winston-Salem, NC</i> | pain | Phase II (336) 480-2100 |
| TC-6499 | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> Targacept <i>Winston-Salem, NC</i> | neuropathic pain | Phase I (888) 825-5249 (336) 480-2100 |
| tezampanel (NGX424) | TorreyPines Therapeutics <i>La Jolla, CA</i> | pain (see also migraine) | Phase II (858) 623-5665 |
| Topamax® topiramate | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> | diabetic neuropathies | Phase III (800) 817-5286 |
| TQ-1011 (ketoprofen intravenous) | TheraQuest Biosciences <i>Blue Bell, PA</i> | post-operative pain | Phase II (610) 272-2071 |

PAIN

| Product Name | Sponsor | Indication | Development Status |
|--|--|--|--|
| TQ-1017 (tramadol extended-release) | Theraquest Biosciences <i>Blue Bell, PA</i> | neuropathic pain | Phase I (610) 272-2071 |
| tramadol CR (controlled-release) | LaboPharm <i>Laval, QC</i> | pain | application submitted (888) 686-1017 |
| tramadol ER (sustained-release) | Cipher Pharmaceuticals <i>Mississauga, ON</i> | pain | application submitted (905) 602-5840 |
| TTP-488 (PF-4494700) | Pfizer <i>New York, NY</i> TransTech Pharma <i>High Point, NC</i> | diabetic neuropathies (see also Alzheimer's disease) | Phase II (860) 732-5156 (336) 841-0300 |
| URG-101 | Urigen Pharmaceuticals <i>Burlingame, CA</i> | pain | Phase II (650) 259-0239 |
| URG-301 | Urigen Pharmaceuticals <i>Burlingame, CA</i> | pain | Phase I (650) 259-0239 |
| Veldona [®] interferon-alpha | Amarillo Biosciences <i>Amarillo, TX</i> | fibromyalgia | Phase II (806) 376-1741 |
| Vestra [™] reboxetine | Pfizer <i>New York, NY</i> | neuropathic pain | Phase II (860) 732-5156 |
| Vicodin CR hydrocodone/ acetaminophen | Abbott Laboratories <i>Abbott Park, IL</i> | back pain | Phase III (847) 937-6100 |
| Vimpat [®] lacosamide | UCB <i>Smyrna, GA</i> | diabetic neuropathic pain (see also epilepsy, migraine) | application submitted (770) 970-7500 |
| | | fibromyalgia | Phase II (770) 970-7500 |
| WAY-126090 | Wyeth <i>Collegeville, PA</i> | neuropathic pain | Phase II (800) 934-5566 |
| xaliproden (SR57746) | sanofi-aventis <i>Bridgewater, NJ</i> | peripheral sensory neuropathies | Phase III (800) 633-1610 |
| Xibrom [™] bromfenac | Ista Pharmaceuticals <i>Irvine, CA</i> | ocular pain (once-daily) | Phase III (949) 788-6000 |
| Xyrem [®] sodium oxybate | Jazz Pharmaceuticals <i>Palo Alto, CA</i> | fibromyalgia syndrome | Phase III (650) 496-3777 |
| ZR 0201 | ZARS <i>Salt Lake City, UT</i> | cancer pain | Phase III (801) 350-0202 |

PARKINSON'S DISEASE

| Product Name | Sponsor | Indication | Development Status |
|---|---|---|-----------------------------|
| Altropane [®] molecular imaging agent | Alseres Pharmaceuticals <i>Hopkinton, MA</i> | imaging agent for early diagnosis of Parkinson's disease | Phase III (508) 497-2360 |

PARKINSON'S DISEASE

| Product Name | Sponsor | Indication | Development Status |
|--|---|--|--|
| aplindore | Neurogen <i>Branford, CT</i> | Parkinson's disease (see also restless legs syndrome) | Phase II (203) 488-8201 |
| apomorphine transdermal patch | Altea Therapeutics <i>Atlanta, GA</i> | Parkinson's disease | Phase I (404) 835-6310 |
| AV-201 (gene therapy) | Genzyme <i>Cambridge, MA</i> | Parkinson's disease | Phase I (617) 252-7000 |
| AZD3241 | AstraZeneca <i>Wilmington, DE</i> | Parkinson's disease | Phase I (800) 236-9933 |
| C-6161 | Merck <i>Whitehouse Station, NJ</i> | Parkinson's disease | Phase I (800) 672-6372 |
| CERE-120 (gene therapy) | Ceregene <i>San Diego, CA</i> Genzyme <i>Cambridge, MA</i> | Parkinson's disease | Phase II (858) 458-8800 (617) 252-7000 |
| CP-101606 (traxoprodil) | Pfizer <i>New York, NY</i> | Parkinson's disease (see also stroke) | in clinical trials (860) 732-5156 |
| creatine monohydrate (PD-02) | Avicena <i>Palo Alto, CA</i> | Parkinson's disease (see also amyotrophic lateral sclerosis, Huntington's disease, muscular dystrophies, other) | Phase III (415) 397-2880 |
| DAR-100 | DarPharma <i>Chapel Hill, NC</i> | Parkinson's disease (see also Alzheimer's disease) | Phase I (919) 403-4348 |
| Duodopa [®] levodopa/carbidopa intraduodenal | Solvay Pharmaceuticals <i>Marietta, GA</i> | severe Parkinson's disease | Phase III (770) 578-9000 |
| fipamezole | Juventus Pharma <i>Turku, Finland</i> Santhera Pharmaceuticals <i>Leistal, Switzerland</i> | Parkinson's disease | Phase II |
| KW-6002 (istradefylline) | Kyowa Pharmaceutical <i>Princeton, NJ</i> | Parkinson's disease | application submitted (609) 919-1100 |
| melperone HCl | Ovation Pharmaceuticals <i>Deerfield, IL</i> | psychosis in Parkinson's disease | Phase II (800) 455-1141 |
| MK-0657 | Merck <i>Whitehouse Station, NJ</i> | Parkinson's disease | Phase I (800) 672-6372 |
| Neupro [®] rotigoline | UCB <i>Smyrna, GA</i> | advanced Parkinson's disease (see also restless legs syndrome) | application submitted (770) 970-7500 |
| NLX-P101 (gene therapy) | Neurologix <i>Fort Lee, NJ</i> | Parkinson's disease | Phase I (201) 592-6451 |
| pardoprunox (SLV308) | Solvay Pharmaceuticals <i>Marietta, GA</i> | Parkinson's disease | Phase III (770) 578-9000 |
| perampanel | Eisai <i>Ridgefield Park, NJ</i> | Parkinson's disease (see also epilepsy, migraine, multiple sclerosis, pain) | Phase III (888) 274-2378 |

PARKINSON'S DISEASE

| Product Name | Sponsor | Indication | Development Status |
|--|--|--|--|
| ReQuip® XL ropinirole HCl (once-daily, controlled-release formulation) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> SkyePharma <i>London, England</i> | Parkinson's disease | application submitted (888) 825-5249 |
| safinamide | EMD Serono <i>Rockland, MA</i> | early-stage Parkinson's disease, mid-to-late-stage Parkinson's disease (see also Alzheimer's disease, restless legs syndrome) | Phase III (800) 283-8088 |
| SCH-412348 | Schering-Plough <i>Kenilworth, NJ</i> | Parkinson's disease | Phase II (908) 298-4000 |
| selegiline transdermal | Somerset Pharmaceuticals <i>Tampa, FL</i> | Parkinson's disease (see also Alzheimer's disease, attention-deficit hyperactivity disorder) | Phase III |
| Spheramine® human retinal pigment epithelial cells on microcarriers (Orphan Drug) | Bayer HealthCare <i>Wayne, NJ</i> Titan Pharmaceuticals <i>South San Francisco, CA</i> | Parkinson's disease | Phase II (888) 842-2937 (650) 244-4990 |
| SYN-115 | Roche <i>Nutley, NJ</i> Synosia Therapeutics <i>South San Francisco, CA</i> | Parkinson's disease | Phase I (973) 235-5000 (650) 244-4850 |
| SYN-118 | Synosia Therapeutics <i>South San Francisco, CA</i> | Parkinson's disease | Phase I (650) 244-4850 |
| talampanel | IVAX <i>Miami, FL</i> | dyskinesia in Parkinson's disease (see also brain tumors, epilepsy) | Phase II (305) 575-6000 |
| V1512 (melevodopa/ carbidopa) | Vernalis <i>Morristown, NJ</i> | Parkinson's disease | Phase II (888) 376-2547 |
| V2006 | Biogen Idec <i>Cambridge, MA</i> Vernalis Pharmaceuticals <i>Morristown, NJ</i> | Parkinson's disease | Phase II (617) 679-2000 (888) 376-2547 |
| XP21279 | Xenoport <i>Santa Clara, CA</i> | Parkinson's disease | Phase I (408) 616-7200 |

RESTLESS LEGS SYNDROME

| Product Name | Sponsor | Indication | Development Status |
|----------------------|--|---|---|
| 1838262 (XP13512) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> XenoPort <i>Santa Clara, CA</i> | restless legs syndrome (see also pain) | Phase III (888) 825-5249 (408) 616-7200 |

RESTLESS LEGS SYNDROME

| Product Name | Sponsor | Indication | Development Status |
|--|--|--|---|
| aplindore | Neurogen <i>Branford, CT</i> | restless legs syndrome (see also Parkinson's disease) | Phase II (203) 488-8201 |
| JZP-7 | Jazz Pharmaceuticals <i>Palo Alto, CA</i> | restless legs syndrome | Phase I (650) 496-3777 |
| Lyrica [®] pregabalin | Pfizer <i>New York, NY</i> | restless legs syndrome (see also epilepsy, pain) | Phase II (860) 732-5156 |
| Neupro [®] rotigotine | UCB <i>Smyrna, GA</i> | restless legs syndrome (see also Parkinson's disease) | application submitted (770) 970-7500 |
| ReQuip [®] ropinirole HCl (extended release) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | restless legs syndrome | Phase III (888) 825-5249 |
| safinamide | EMD Serono <i>Rockland, MA</i> | restless legs syndrome (see also Alzheimer's disease, Parkinson's disease) | Phase II (800) 283-8088 |

SLEEP DISORDERS

| Product Name | Sponsor | Indication | Development Status |
|---|--|---|------------------------------|
| 189254 (histamine H3 antagonist) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | narcolepsy | Phase II (888) 825-5249 |
| 649868 | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | insomnia | Phase I/II (888) 825-5249 |
| adipiplon (NG2-73) | Neurogen <i>Branford, CT</i> | insomnia | Phase II (203) 488-8201 |
| APD-125 | Arena Pharmaceuticals <i>San Diego, CA</i> | insomnia | Phase II (858) 452-7200 |
| AVE0657 | sanofi-aventis <i>Bridgewater, NJ</i> | sleep apnea syndrome | Phase I (800) 633-1610 |
| AZ-007 (zoleplon inhalation) | Alexza Pharmaceuticals <i>Mountain View, CA</i> | insomnia | Phase I (650) 944-7000 |
| BGC 200166 | BTG <i>West Conshohocken, PA</i> | sleep apnea syndrome | Phase II (610) 278-1660 |
| Circadin [®] melatonin controlled-release | Neurim Pharmaceuticals <i>Tel-Aviv, Israel</i> | insomnia | Phase III |
| CX717 | Cortex Therapeutics <i>Menlo Park, CA</i> | sleep disorders (see also Alzheimer's disease) | Phase II (650) 327-3270 |
| EMD-281014 | Eli Lilly <i>Indianapolis, IN</i> | insomnia | Phase I (800) 545-5979 |
| eplivanserin (SR46349) | sanofi-aventis <i>Bridgewater, NJ</i> | insomnia | Phase III (800) 633-1610 |

SLEEP DISORDERS

| Product Name | Sponsor | Indication | Development Status |
|--|---|--|---|
| EVT-201 | Evotec <i>Hamburg, Germany</i> | insomnia | Phase II |
| Gabitril® tiagabine | Cephalon <i>Frazer, PA</i> | insomnia (see also pain) | Phase II (610) 344-0200 |
| indiplon (immediate-release) | Neurocrine Biosciences <i>San Diego, CA</i> | insomnia | application submitted (585) 617-7600 |
| Intermezzo™ zolpidem sublingual | Transcept Pharmaceuticals <i>Pt. Richmond, CA</i> | insomnia | Phase III |
| ITI-007 | IntraCellular Therapies <i>New York, NY</i> | insomnia | Phase II (212) 923-3344 |
| LY-2422347 (pruvanserin) | Eli Lilly <i>Indianapolis, IN</i> | insomnia | Phase II (800) 545-5979 |
| LY-2624803 | Eli Lilly <i>Indianapolis, IN</i> | insomnia | Phase II (800) 545-5979 |
| MK-0454 | Merck <i>Whitehouse Station, NJ</i> | insomnia | Phase I (800) 672-6372 |
| MK-8998 | Merck <i>Whitehouse Station, NJ</i> | insomnia | Phase I (800) 672-6372 |
| NBI-75043 | Neurocrine Biosciences <i>San Diego, CA</i> | insomnia | Phase I (858) 617-7600 |
| ORG 50081 (esmirtazapine) | Organon USA <i>Roseland, NJ</i> | insomnia | Phase III (973) 325-4500 |
| paliperidone (extended-release) | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> | insomnia | Phase II (800) 817-5286 |
| PD-200390 | Pfizer <i>New York, NY</i> | insomnia | Phase II (860) 732-5156 |
| PD-299685 | Pfizer <i>New York, NY</i> | insomnia | Phase II (860) 732-5156 |
| pimavanserin | ACADIA Pharmaceuticals <i>San Diego, CA</i> | insomnia (see also other) | Phase II (858) 558-2871 |
| Rozerem™ ramelteon | Takeda Pharmaceuticals North America <i>Deerfield, IL</i> | circadian rhythm sleep disorders, Alzheimer's sleep/wake disturbance | Phase II (877) 582-5332 |
| SO-101 | Somaxon Pharmaceuticals <i>Del Mar, CA</i> | insomnia | application submitted (858) 480-0400 |
| Sonata® zaleplon (extended-release) | King Pharmaceuticals <i>Bristol, TN</i> | insomnia | Phase II (800) 776-3637 |
| Sublinox™ zolpidem sublingual | Orexo <i>Uppsala, Sweden</i> | insomnia | Phase III |

SLEEP DISORDERS

| Product Name | Sponsor | Indication | Development Status |
|---|---|----------------------|---|
| TIK-301 | Tikvah Therapeutics <i>Atlanta, GA</i> | insomnia | Phase II (404) 920-3180 |
| VEC-162 | Vanda Pharmaceuticals <i>Rockville, MD</i> | insomnia | Phase III (240) 599-4500 |
| volinanserin (M100907) | sanofi-aventis <i>Bridgewater, NJ</i> | insomnia | Phase III (800) 633-1610 |
| VSF-173 | Vanda Pharmaceuticals <i>Rockville, MD</i> | excessive sleepiness | Phase II (240) 599-4500 |
| ZolpiMist™ zolpidem oral spray | NovaDel Pharma <i>Flemington, NJ</i> | insomnia | application submitted (908) 782-3431 |

SPINAL CORD INJURY

| Product Name | Sponsor | Indication | Development Status |
|---|--|---|--|
| ATI-355 | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | spinal cord injury | Phase I (888) 669-6682 |
| BA 210 | Alseres Pharmaceuticals <i>Hopkinton, MA</i> BioAxone Therapeutic <i>Montreal, Quebec</i> | acute thoracic and cervical spinal cord injury | Phase I (508) 497-2360 |
| MAb-IN1 | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | spinal cord injury | Phase I (888) 669-6682 |
| ProCord autologous macrophages cell therapy | Proneuron Biotechnologies <i>Los Angeles, CA</i> | spinal cord injury | Phase II www.proneuron.com |

STROKE

| Product Name | Sponsor | Indication | Development Status |
|--------------------------------------|---|--|---|
| 813893 (factor Xa inhibitor) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | prevention of stroke in atrial fibrillation | Phase I (888) 825-5249 |
| alfimeprase | Nuvelo <i>San Carlos, CA</i> | stroke | Phase II (650) 517-8000 |
| apixaban (factor Xa inhibitor) | Bristol-Myers Squibb <i>Princeton, NJ</i> Pfizer <i>New York, NY</i> | prevention of stroke in atrial fibrillation | Phase III (212) 546-4000 (860) 732-5156 |
| arundic acid | Merck <i>Whitehouse Station, NJ</i> | stroke (see also Alzheimer's disease) | Phase II (800) 672-6372 |
| BVI-007 | BioVascular <i>San Diego, CA</i> | stroke | Phase I (858) 455-5000 |

STROKE

| Product Name | Sponsor | Indication | Development Status |
|-------------------------------------|--|---|---|
| Cerebril™ tramiprosate | Neurochem <i>Laval, Quebec</i> | hemorrhagic stroke due to cerebral amyloid angiopathy | Phase II (450) 680-4500 |
| clazosentan | Actelion Pharmaceuticals US <i>South San Francisco, CA</i> | prevention of vasospasm following subarachnoid hemorrhage | Phase II (650) 624-6900 |
| CP-101606 (traxoprodil) | Pfizer <i>New York, NY</i> | stroke (see also Parkinson's disease) | Phase II (860) 732-5156 |
| desmoteplase | Lundbeck Research USA <i>Paramus, NJ</i> | ischemic stroke | Phase III (201) 261-1331 |
| MC-1 | Medicure <i>Winnipeg, Manitoba</i> | stroke | Phase I (204) 487-7412 |
| MK-0724 | Merck <i>Whitehouse Station, NJ</i> | stroke | Phase II (800) 672-6372 |
| NA-1 | Arbor Vita <i>Sunnyvale, CA</i> | stroke | Phase I (408) 585-3900 |
| NEU2000 | Amkor Pharma <i>Sammamish, WA</i> | stroke | Phase I (206) 694-4424 |
| NTx™-265 | Stem Cell Therapeutics <i>Calgary, AB</i> | stroke | Phase II (403) 245-5495 |
| rivaroxaban | Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> | stroke | Phase III (888) 842-2937 (800) 817-5286 |
| S-0139 (endothelin A antagonist) | Shionogi USA <i>Florham Park, NJ</i> | stroke | Phase II (973) 966-6900 |
| SUN N4057 (piclozotan) | Asubio Pharma <i>Rochelle Park, NJ</i> | acute ischemic stroke | Phase II (201) 368-5020 |
| SUN N8075 | Asubio Pharma <i>Rochelle Park, NJ</i> | acute ischemic stroke | Phase I (201) 368-5020 |
| tenecteplase | Genentech <i>South San Francisco, CA</i> | stroke | Phase II (650) 225-1000 |
| TS-011 | Taisho Pharmaceutical <i>Morristown, NJ</i> | stroke | Phase I |
| V10153 | Vernalis Pharmaceuticals <i>Morristown, NJ</i> | stroke | Phase II (888) 376-2547 |
| Viprinex™ ancrod | Neurobiological Technologies <i>Richmond, CA</i> | acute ischemic stroke | Phase III (510) 262-1730 |
| zonampanel (YM-872) | Astellas Pharma US <i>Deerfield, IL</i> | stroke | Phase II (800) 727-7003 |

SYSTEMIC LUPUS ERYTHEMATOSUS

| Product Name | Sponsor | Indication | Development Status |
|--|--|--------------------------------------|--|
| AMG 557 | Amgen <i>Thousand Oaks, CA</i> | systemic lupus erythematosus (SLE) | Phase I (805) 447-1000 |
| AMG 623 | Amgen <i>Thousand Oaks, CA</i> | SLE | Phase I (805) 447-1000 |
| atacept (TACI-Ig) | EMD Serono <i>Rockland, MA</i> ZymoGenetics <i>Seattle, WA</i> | SLE (see also multiple sclerosis) | Phase I (800) 283-8088 (800) 775-6686 |
| belimumab | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | SLE | Phase III (888) 825-5249 |
| CNTO 136 | Centocor <i>Horsham, PA</i> | SLE | Phase II (610) 651-6000 |
| CPG 52364 | Coley Pharmaceutical <i>Wellesley, MA</i> | SLE | Phase I (781) 431-9000 |
| edratide | Teva Pharmaceuticals North America <i>North Wales, PA</i> | SLE | Phase II (215) 591-3000 |
| epratuzumab | UCB <i>Smyrna, GA</i> | SLE | Phase III (770) 970-7500 |
| MEDI-545 | Medarex <i>Princeton, NJ</i> MedImmune <i>Gaithersburg, MD</i> | SLE | Phase I (609) 430-2880 (301) 398-0000 |
| ocrelizumab (2nd generation anti-CD20) | Biogen Idec <i>Cambridge, MA</i> Genentech <i>South San Francisco, CA</i> | SLE (see also multiple sclerosis) | Phase III (617) 679-2000 (650) 225-1000 |
| Prestara™ prasterone | Genelabs <i>Redwood City, CA</i> Watson Pharmaceuticals <i>Corona, CA</i> | SLE | Phase III (650) 369-9500 (800) 249-5499 |
| R1569 | Roche <i>Nutley, NJ</i> | SLE | Phase I (973) 235-5000 |
| rhuMab IFNalpha | Genentech <i>South San Francisco, CA</i> | SLE | Phase I (650) 225-1000 |
| Rituxan® rituximab | Biogen Idec <i>Cambridge, MA</i> Genentech <i>South San Francisco, CA</i> | SLE (see also multiple sclerosis) | Phase II/III (617) 679-2000 (650) 225-1000 |

OTHER

| Product Name | Sponsor | Indication | Development Status |
|---|--|--|---|
| 249320 | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | neuronal injury | Phase I (888) 825-5249 |
| ABT-107 | Abbott Laboratories <i>Abbott Park, IL</i> | central nervous system (CNS) disorders (see also Alzheimer's disease) | Phase I (847) 937-6100 |
| AST-914 | Ariston Pharmaceuticals <i>Framingham, MA</i> | movement disorders | in clinical trials (508) 665-4260 |
| autologous cultured urological tissue cells | Tengion <i>East Norriton, PA</i> | neurogenic bladder | Phase II www.tengion.com |
| AV-133 (imaging agent) | Avid Radiopharmaceuticals <i>Philadelphia, PA</i> | detection of neurodegenerative disorders | Phase I (215) 966-6208 |
| AV-650 | Avigen <i>Alameda, CA</i> | spasticity | Phase II (510) 748-7150 |
| Avonex® interferon beta-1a | Biogen Idec <i>Cambridge, MA</i> | chronic inflammatory demyelinating polyneuropathy | Phase II (617) 679-2000 |
| AVP923 | Avanir Pharmaceuticals <i>San Diego, CA</i> | pseudobulbar affect (emotional lability)—pathological laughing or crying associated with neurologic disorders (see also pain) | application submitted (858) 622-5200 |
| Botox® botulinum toxin type A (Orphan Drug) | Allergan <i>Irvine, CA</i> | neurogenic bladder, spasticity associated with spectrum disorder, juvenile cerebral palsy, spasticity (see also migraine, pain) | Phase III (800) 433-8871 |
| | | Tourette's syndrome | in clinical trials (800) 433-8871 |
| carbetocin intranasal | Nastech Pharmaceutical <i>Bothell, WA</i> | autism spectrum disorder | Phase I (425) 908-3600 |
| Coprexa™ tetrathiomolybdate | Pipex Pharmaceuticals <i>Ann Arbor, MI</i> | Wilson's disease | Phase III (734) 332-7800 |
| creatine monohydrate (CMT-02) | Avicena <i>Palo Alto, CA</i> | Charcot-Marie-Tooth syndrome (see also amyotrophic lateral sclerosis, Huntington's disease, muscular dystrophies, Parkinson's disease) | Phase I (415) 397-1880 |
| Flomax® tamsulosin | Astellas Pharma US <i>Deerfield, IL</i> | neurogenic bladder | Phase III (800) 727-7003 |
| fluoxetine-rapid dissolve | Neuropharm <i>Surrey, United Kingdom</i> | autism spectrum disorder | Phase III |
| Fx-1006A | FoldRx Pharmaceuticals <i>Cambridge, MA</i> | familial amyloid polyneuropathy | Phase II (617) 252-5500 |

OTHER

| Product Name | Sponsor | Indication | Development Status |
|---|---|---|---|
| hCNS-SC (adult neural stem cell therapy) | StemCells <i>Palo Alto, CA</i> | neuronal ceroid lipofuscinosis | Phase I (650) 475-3100 |
| isovaleramide (NPS-1776) | NPS Pharmaceuticals <i>Salt Lake City, UT</i> | CNS disorders | Phase II (801) 583-4939 |
| KRX-0501 | Keryx Biopharmaceuticals <i>New York, NY</i> | neurological disorders | Phase I (212) 531-5965 |
| levtofisopam | Vela Pharmaceuticals <i>Ewing, NJ</i> | CNS disorders | Phase I (609) 771-8660 |
| MK-4305 | Merck <i>Whitehouse Station, NJ</i> | neurological disorders | Phase I (800) 672-6372 |
| MM-093 | Merrimack Pharmaceuticals <i>Cambridge, MA</i> | myasthenia gravis (see also multiple sclerosis) | Phase I (617) 441-1000 |
| ORG 25935 | Organon USA <i>Roseland, NJ</i> | neurological disorders | Phase II (973) 325-4500 |
| ORG 26041 | Organon USA <i>Roseland, NJ</i> | neurological disorders | Phase I (973) 325-4500 |
| ORG 26576 | Organon USA <i>Roseland, NJ</i> | neurological disorders | Phase I (973) 325-4500 |
| ORG 50189 | Organon USA <i>Roseland, NJ</i> | neurological disorders | Phase I (973) 325-4500 |
| osteopontin | EMD Serono <i>Rockland, MA</i> | neurological disorders | Phase I (800) 283-8088 |
| Oxycyte™ perfluorocarbon oxygen carrier | Synthetics Blood International <i>Costa Mesa, CA</i> | traumatic brain injury | Phase II (800) 809-6054 |
| pagoclone | Indevus Pharmaceuticals <i>Lexington, MA</i> | stuttering | Phase II (781) 861-8444 |
| pimavanserin (ACP-103) | ACADIA Pharmaceuticals <i>San Diego, CA</i> | movement disorders (see also sleep disorders) | Phase I (858) 558-2871 |
| PN401 (triacetyluridine) | Wellstat BioPharma <i>Gaithersburg, MD</i> | neurodegenerative disease | Phase I (240) 631-2500 |
| PNU 96391 | Pfizer <i>New York, NY</i> | movement disorders | Phase I (860) 732-5156 |
| PW4159 | Penwest Pharmaceuticals <i>Danbury, CT</i> | spasticity | Phase I (203) 796-3700 |
| Reloxin® botulinum toxin A | Ipsen <i>Milford, MA</i> | cervical dystonia (spasmodic torticollis) (see also pain) | application submitted (508) 478-8900 |
| | | ----- spasticity | Phase III (508) 478-8900 |
| SLV-330 | Solvay Pharmaceuticals <i>Marietta, GA</i> | CNS disorders | Phase I (770) 578-9000 |

OTHER

| Product Name | Sponsor | Indication | Development Status |
|--|---|-------------------------------|---|
| SLV-334 | Solvay Pharmaceuticals <i>Marietta, GA</i> | brain damage, neuroprotection | Phase I (770) 578-9000 |
| SNT-MC17 (idebenone) (Orphan Drug) | Santhera Pharmaceuticals <i>Liestal, Switzerland</i> National Institutes of Health <i>Bethesda, MD</i> | Friedreich's ataxia | Phase III www.santhera.com |
| valroceamide (SPD493) | Shire <i>Wayne, PA</i> | CNS disorders | Phase I (484) 595-8800 |
| XP19986 | XenoPort <i>Santa Clara, CA</i> | spasticity | Phase II (408) 616-7200 |
| XY-2405 anatibant (Orphan Drug) | Xytis Pharmaceuticals <i>San Mateo, CA</i> | traumatic brain injury | Phase I www.xytis.com |
| Zemuron [®] rocuronium bromide | Organon USA <i>Roseland, NJ</i> | hypertonia | Phase III (973) 325-4500 |
| Zyprexa [®] olanzapine | Eli Lilly <i>Indianapolis, IN</i> | Tourette's syndrome | in clinical trials (800) 545-5979 |

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 18, 2008.** The information may not be comprehensive. For more specific information about a particular product, contact the individual company directly or go to www.clinicaltrials.gov. The entire series of *Medicines in Development* is available on PhRMA's web site.

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Alzheimer's disease—A progressive, 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).

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.

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

migraine—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.

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.

nociceptive pain—Pain caused by an injury that stimulates pain receptors that are located on the tips of nerve cells, which recognize and react to pressure, extreme temperatures (hot or cold), or substances released by other cells. Nociceptive pain may be accompanied by inflammation. Infections, burns, cuts, a severe lack of oxygen in the blood, and stretching of or pressure within an organ can injure tissues and cause nociceptive pain.

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.

postherpetic 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 NEUROLOGICAL DISORDERS IN THE UNITED STATES

Alzheimer's Disease/Dementias¹

- Today, more than 5 million people are living with **Alzheimer's**—every 72 seconds, someone develops the disease. Some 4.9 million people with Alzheimer's are age 65 and older, but at least 500,000 people younger than age 65 either have early-onset Alzheimer's or another **dementia**.
 - **Alzheimer's disease** is the most common **dementia**, accounting for 50 percent to 70 percent of cases. **Vascular dementia** (also called multi-infarct dementia, post-stroke dementia, or vascular **cognitive impairment**) is widely considered the second most common type after Alzheimer's.
 - In 2000, an estimated 411,000 new cases of **Alzheimer's** were diagnosed. That number is expected to increase to 454,000 new cases a year by 2010; 615,000 annually by 2030; and 959,000 new cases a year by 2050.
 - In 2004, **Alzheimer's** was listed as the “underlying cause of death” for 65,829 Americans. That year, Alzheimer's was the seventh leading cause of death for people of all ages and the fifth in people age 65 and older.
 - Some 70 percent of people with **Alzheimer's** and other **dementias** live at home, where they are cared for by family and friends. The unpaid caregivers provided the nation with an economic asset worth almost \$83 billion in 2005, based on their hours of care.
 - The direct and indirect costs of **Alzheimer's** and other **dementias** amount to more than \$148 billion annually.
-

Amyotrophic Lateral Sclerosis (ALS)²

- Approximately 5,600 people in the United States are diagnosed with amyotrophic lateral sclerosis (ALS) each year, an incidence rate that is five times higher than **Huntington's disease** and about equal to **multiple sclerosis**. It is estimated that as many as 30,000 Americans may have the disease at any given time. ALS usually strikes people between the ages of 40 and 70. It is responsible for nearly 2 deaths per 100,000 population annually. More people die every year of ALS than of Huntington's disease or multiple sclerosis.
-

Attention-Deficit Hyperactivity Disorder (ADHD)

- It is estimated that between 3 percent to 5 percent of children have **attention-deficit hyperactivity disorder (ADHD)**, or some 2 million children in this country. In a classroom of 25 to 30 children, it is likely that at least one will have ADHD.³ ADHD is one of the most common reasons children are referred for mental health services. The disorder is three to four times more common in boys than in girls, although both genders are affected.⁴
-

Brain Tumors⁵

- In 2008, an estimated 44,865 new cases of **primary brain tumors** (both malignant and benign) are expected to be diagnosed. **Brain tumors** are the most common solid tumors in children, and the leading cause of death from solid tumors. Brain tumors are the second most frequent malignancy of childhood and the second leading cause of cancer-related deaths (after leukemia) in children under the age of 20.
 - **Gliomas** represent 40 percent of all brain tumors and 78 percent of all malignant tumors. **Glioblastomas** represent 20.3 percent of all primary brain tumors, and 50.7 percent of all gliomas.
-

Epilepsy⁶

- **Epilepsy** and **seizures** affect more than 3 million Americans of all ages. Ten percent of the U.S. population will experience a seizure in their lifetime, and 3 percent will develop epilepsy by age 75.
 - Each year, 300,000 people have a first convulsion. Of that total, 120,000 are children under age 18, and between 75,000 and 100,000 are under age 5 who have experienced a febrile (fever-caused) **seizure**. The incidence is highest under the age of 2 and over age 65. In 70 percent of new cases, no cause is apparent.
 - The estimated direct and indirect costs of **epilepsy** and **seizures** amount to \$12.5 billion annually.
-

Huntington's Disease⁷

- 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.

SELECTED FACTS ABOUT NEUROLOGICAL DISORDERS IN THE UNITED STATES

Migraine/Headache⁸

- **Migraines** affect 29.5 million Americans. The headaches are most commonly experienced between the ages of 15 and 55. Women are almost three times more likely to suffer from migraines than men.
 - 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.
-

Multiple Sclerosis⁹

- Some 400,000 Americans have **multiple sclerosis (MS)**, and every week another 200 are diagnosed. Twice as many women as men have MS. Most people are diagnosed between the ages of 20 and 50. Worldwide, MS may affect 2.5 million people.
-

Pain

- Some 26 percent of Americans age 20 and older—an estimated 76.5 million people—report that they have had a problem with **pain** of any sort that persisted for more than 24 hours in duration (not including acute pain). More women (27.1 percent) than men (24.4 percent) report that they have pain.¹⁰
 - When asked about four common types of pain, respondents to a National Institute of Health Statistics survey indicated that **low back pain** was the most common (27 percent), followed by severe **headache** or **migraine pain** (15 percent), **neck pain** (15 percent), and **facial ache** or pain (4 percent). **Back pain** is the leading cause of disability in Americans under age 45. More than 26 million Americans between the ages of 20-64 experience frequent back pain.¹⁰
 - An estimated 70 percent of those with cancer experience significant **pain** during their illness, yet fewer than half receive adequate treatment for their pain. More than half of all hospitalized patients experienced pain in the last days of their lives. Although therapies are present to alleviate most pain for those dying of cancer, research shows that 50 percent to 75 percent of patients die in moderate to severe pain.¹⁰
 - **Peripheral neuropathy** affects at least 20 million people in this country. Nearly 60 percent of all people with diabetes suffer from peripheral neuropathy.¹¹
 - The annual cost of **chronic pain** in the United States, including healthcare expenses, lost income, and lost productivity, is estimated to be \$100 billion.¹⁰
-

Parkinson's Disease (PD)¹²

- Today, 1.5 million Americans have **Parkinson's**, and each year 60,000 new cases are diagnosed. Parkinson's affects both men and women in almost equal numbers. The condition usually develops after age 65, but 15 percent of those diagnosed with Parkinson's are under age 50. After **Alzheimer's disease**, Parkinson's is the most common neurodegenerative disease.
-

Sleep Disorders¹³

- Approximately 70 million people in the United States are affected by a sleep problem—about 40 million Americans suffer from chronic **sleep disorders**, and up to 30 million are affected by intermittent sleep-related problems. As many as 47 million adults may be putting themselves at risk for injury, health, and behavior problems because they aren't meeting their minimum sleep needs in order to be fully alert the next day.
- **Narcolepsy** is believed to affect some 293,000 people in the United States.
- Approximately 12 million Americans have **restless legs syndrome**.
- **Sleep apnea** affects as many as 18 million people. Untreated sleep apnea may cause \$3.4 billion in additional medical costs.
- 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.

SELECTED FACTS ABOUT NEUROLOGICAL DISORDERS IN THE UNITED STATES

Spinal Cord Injury¹⁴

- 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. 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 nearly \$3 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.
-

Stroke¹⁵

- About 700,000 Americans will have a **stroke** this year—that's someone every 45 seconds.
 - Stroke kills more than 150,000 people a year—that's about 1 of every 16 deaths. Of every five people who die from stroke, about two are men and three are women. Stroke is the third leading cause of death behind heart disease and cancer. About every 3 minutes, someone dies of stroke.
 - In 2007, Americans will pay about \$63 billion for **stroke**-related medical costs and disability.
-

Systemic Lupus Erythematosus

- **Lupus** affects between 1.5 million to 2 million Americans, more than 90 percent of whom are women in their childbearing years. Each year, more than 16,000 Americans develop lupus.¹⁶ African-American women are three times more likely to get lupus than Caucasian women.¹⁷
-

Other

- An estimated 800,000 people in the United States have **cerebral palsy**, and about 10,000 babies per year will develop the disorder.¹⁸ Today, more people have cerebral palsy than any other developmental disability, including Down syndrome, **epilepsy**, and autism.¹⁹
 - In 2003 dollars, the average lifetime cost of **cerebral palsy** is an estimated \$921,000, *not* including hospital visits, emergency room visits, residential care, and other out-of-pocket expenses.¹⁸
 - Of the 1.4 million people who sustain a **traumatic brain injury (TBI)** each year: 50,000 die; 235,000 are hospitalized; and 1.1 million are treated and released from an emergency department. Males are about 1.5 times as likely as females to sustain a **TBI**. The direct medical costs and indirect costs of **TBI** totaled an estimated \$56.3 billion in 1995.²⁰
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Sources:

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2. ALS Association (www.alsa.org)
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4. Mental Health America (www.nmha.org)
5. American Brain Tumor Association (www.abta.org)
6. Epilepsy Foundation (www.epilepsyfoundation.org)
7. National Institute of Neurological Disorders and Stroke (www.ninds.nih.gov)
8. National Headache Foundation (www.headaches.org)
9. National MS Society (www.nationalmssociety.org)
10. Pain Foundation (www.painfoundation.org)
11. neurologychannel (www.neurologychannel.com)
12. National Parkinson Foundation (www.parkinson.org)
13. Sleep Foundation (www.sleepfoundation.org)
14. Spinal Cord Injury Information Network (www.spinalcord.uab.edu)
15. American Heart Association (www.americanheart.org)
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17. Lupus Research Institute (www.lupusresearchinstitute.org)
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19. Cerebral Palsy Facts (www.cerebralpalsyfacts.com)
20. Brain Injury Association of America (www.biausa.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 29 new therapeutics approved by the FDA in 2006 was 15.6 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 \$44.5 billion in research and development in 2007.

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

The ALS Association
American Brain Tumor Association
American Headache Society
American Nurses Association
American Pain Foundation
American Parkinson Disease Association
Brain Injury Association of America
Epilepsy Foundation
Huntington's Disease Society of America
Interamerican College of Physicians & Surgeons
MAGNUM, The National Migraine Association
National Alliance for Hispanic Health
National Black Nurses Association
National Headache Foundation
National Medical Association
Parkinson's Disease Foundation

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