

Women

PRESENTED BY AMERICA'S PHARMACEUTICAL RESEARCH COMPANIES

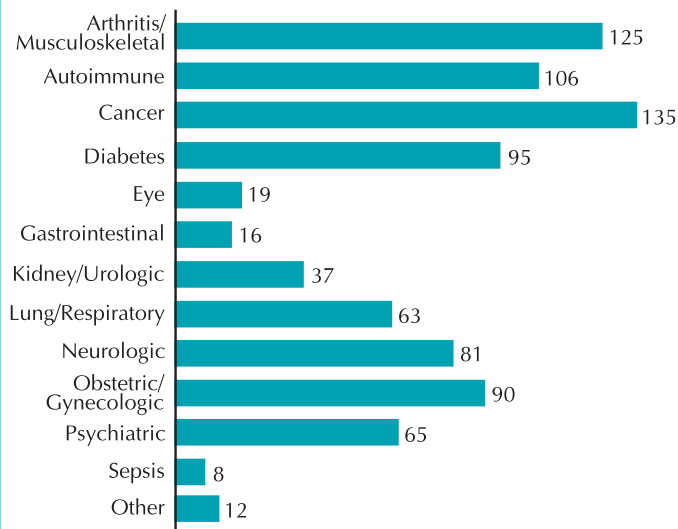
More Than 700 Medicines Are in Testing for Diseases Of Major Concern to American Women

America's pharmaceutical research companies are developing 771 medicines for diseases that disproportionately affect American women. The medicines in the pipeline for women (either in clinical trials or awaiting approval at the Food and Drug Administration) include:

- 135 for female specific cancers, including 95 for breast cancer, 47 for ovarian cancer, and 17 for cervical cancer.
- 125 for arthritis/musculoskeletal disorders. Arthritis affects 41 million women, accounting for 70 percent of all rheumatoid arthritis sufferers and nearly 64 percent of Americans with osteoarthritis.
- 90 for obstetric/gynecologic conditions.
- 106 for autoimmune diseases, which collectively afflict 23.5 million Americans, most of them women.
- 95 for diabetes, which is reaching epidemic proportions, particularly among women and minorities. More than 9 million women over the age of 20 have diabetes, including one-third who do not know it.
- 65 for depression and anxiety. Almost twice as many women as men suffer from these disorders.
- 56 for Alzheimer's disease, which affects more women than men because women tend to live longer.
- 59 for asthma, which affected more than 20 million Americans in 2004, with the prevalence rate for women being 24 percent higher than for men.

Among the potential new medicines in development for women:

- A medicine for metastatic breast cancer designed to bind to and inhibit a protein that plays a critical role in the formation of new blood vessels that feed the tumor.
- A first-in-class medicine in development for type 2 diabetes shown in clinical trials to significantly improve long-term glycemic control.
- A medicine in development for psoriasis designed to selectively inhibit proteins that are responsible for inflammation.

Medicines and Vaccines in Development for Women*

* Some medicines are listed in more than one category.

In separate reports, PhRMA has found that researchers are working on 277 medicines for heart disease and stroke—which kill half a million women each year—and 96 medicines for lung cancer, the leading cancer killer of women (see page 55 for details).

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

Billy Tauzin
President and CEO
PhRMA

Medicines in Development for Women

ARTHRITIS/MUSCULOSKELETAL DISORDERS

| Product Name | Company | Indication | Development Status* |
|--|---|---|--|
| 681323 (p38 kinase inhibitor, oral) | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | rheumatoid arthritis | Phase II (888) 825-5249 |
| 751689 (calcium antagonist) | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | postmenopausal osteoporosis | Phase I (888) 825-5249 |
| 856553 (p38 kinase inhibitor, oral) | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | rheumatoid arthritis | Phase II (888) 825-5249 |
| ABT-963 | Abbott Laboratories Abbott Park, IL | osteoarthritis | Phase I (847) 937-6100 |
| ACE-011 | Acceleron Pharma Cambridge, MA | postmenopausal osteoporosis | Phase I (617) 576-2220 |
| Actemra™ tocilizumab | Roche Nutley, NJ | rheumatoid arthritis (see also autoimmune) | Phase III (973) 235-5000 |
| ACZ 885 | Novartis Pharmaceuticals East Hanover, NJ | rheumatoid arthritis | Phase II (888) NOW-NOVA |
| AGG-523 | Wyeth Pharmaceuticals Collegeville, PA | osteoarthritis | Phase I (800) 934-5556 |
| AME 527 | Applied Molecular Evolution San Diego, CA | rheumatoid arthritis | Phase I (858) 597-4990 |
| Amevive® alefacept | Biogen Idec Cambridge, MA | rheumatoid arthritis (see also autoimmune) | Phase II (617) 679-2000 |
| AMG 108 | Amgen Thousand Oaks, CA | rheumatoid arthritis | Phase II (805) 447-1000 |
| AMG 714 | Amgen Thousand Oaks, CA Genmab Princeton, NJ | rheumatoid arthritis (see also autoimmune) | Phase II (805) 447-1000 (609) 430-2841 |
| AMG 719 | Amgen Thousand Oaks, CA | rheumatoid arthritis | Phase II (805) 447-1000 |
| apilimod (STA-5326) | Synta Pharmaceuticals Lexington, MA | rheumatoid arthritis | Phase II (781) 274-8200 |
| apratostat (TMI-005) | Amgen Thousand Oaks, CA Wyeth Pharmaceuticals Collegeville, PA | rheumatoid arthritis | Phase II (805) 447-1000 (800) 934-5556 |

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

ARTHRITIS/MUSCULOSKELETAL DISORDERS

| Product Name | Company | Indication | Development Status |
|--|---|---|---|
| Aprela™ conjugated estrogens/ bazedoxifene | Ligand Pharmaceuticals <i>San Diego, CA</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i> | postmenopausal osteoporosis prevention (see also obstetric/gynecologic) | Phase III (858) 550-7500 (800) 934-5556 |
| Arava® leflunomide | Pfizer <i>New York, NY</i> | juvenile rheumatoid arthritis | application submitted (860) 732-5156 |
| Arcoxia™ etoricoxib | Merck <i>Whitehouse Station, NJ</i> | osteoarthritis (see also obstetric/gynecologic) | application submitted (800) 672-6372 |
| | | rheumatoid arthritis | Phase III (800) 672-6372 |
| ARRY-162 | Array BioPharma <i>Boulder, CO</i> | rheumatoid arthritis | Phase I (303) 381-6600 |
| arzoifene (next-generation SERM) | Eli Lilly <i>Indianapolis, IN</i> | postmenopausal osteoporosis prevention and treatment (see also cancer) | Phase III (317) 276-2000 |
| AT-001 | Androclus Therapeutics <i>San Diego, CA</i> | rheumatoid arthritis | Phase II (858) 909-0020 |
| atacept | EMD Serono <i>Rockland, MA</i> ZymoGenetics <i>Seattle, WA</i> | rheumatoid arthritis (see also autoimmune) | Phase II (800) 283-8088 (800) 775-6686 |
| AVE1701 (MLN3701) | Millennium Pharmaceuticals <i>Cambridge, MA</i> sanofi-aventis <i>Bridgewater, NJ</i> | rheumatoid arthritis | Phase I (800) 390-5663 (800) 633-1610 |
| AVE9897 (MLN3897) | Millennium Pharmaceuticals <i>Cambridge, MA</i> sanofi-aventis <i>Bridgewater, NJ</i> | rheumatoid arthritis (see also autoimmune) | Phase II (800) 390-5663 (800) 633-1610 |
| AZD 5672 | AstraZeneca <i>Wilmington, DE</i> | rheumatoid arthritis | Phase I (800) 236-9933 |
| AZD 6703 | AstraZeneca <i>Wilmington, DE</i> | rheumatoid arthritis | Phase I (800) 236-9933 |
| BA-058 | Radius <i>Cambridge, MA</i> | osteoporosis | Phase II (617) 551-4700 |
| belimumab | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> Human Genome Sciences <i>Rockville, MD</i> | rheumatoid arthritis (see also autoimmune) | Phase II (888) 825-5249 (301) 309-8504 |
| bicifadine | XTL Biopharmaceuticals <i>Valley Cottage, NY</i> | osteoarthritis | Phase II (845) 267-0707 |

ARTHRITIS/MUSCULOSKELETAL DISORDERS

| Product Name | Company | Indication | Development Status |
|--|--|---|---|
| BR3-Fc | Biogen Idec Cambridge, MA Genentech South San Francisco, CA | rheumatoid arthritis (see also autoimmune) | Phase II (617) 679-2000 (650) 225-1000 |
| C-3578 | Merck Whitehouse Station, NJ | osteoporosis | Phase II (800) 672-6372 |
| C-8500 | Merck Whitehouse Station, NJ | osteoporosis | Phase I (800) 672-6372 |
| calcitonin oral | Unigene Laboratories Fairfield, NJ | postmenopausal osteoporosis | Phase II (973) 882-0860 |
| CDP-7851 (sclerostin Ab) | Amgen Thousand Oaks, CA | osteoporosis | Phase I (805) 447-1000 |
| CE-224535 | Pfizer New York, NY | rheumatoid arthritis | Phase I (860) 732-5156 |
| CellCept® mycophenolate mofetil | Aspreva Pharmaceuticals Victoria, BC Roche Nutley, NJ | rheumatoid arthritis (see also kidney/urologic) | Phase III (250) 744-2488 (973) 235-5000 |
| Cenestin® conjugated estrogens oral | Duramed Pharmaceuticals Cincinnati, OH | postmenopausal osteoporosis prevention (see also obstetric/gynecologic) | Phase I (513) 731-9900 |
| CF-101 | Can-Fite BioPharma Lexington, MA | rheumatoid arthritis | Phase II (781) 778-0417 |
| CH-1504 | Chelsea Therapeutics Charlotte, NC | rheumatoid arthritis (see also autoimmune) | Phase I (704) 341-1516 |
| chondroitin sulfate | Bioiberica Barcelona, Spain | osteoarthritis | Phase III www.bioiberica.com |
| Cimzia™ certolizumab pegol | Nektar Therapeutics San Carlos, CA | rheumatoid arthritis | Phase III (650) 631-3100 |
| CJ-023423 | Pfizer New York, NY | osteoarthritis | Phase II (860) 732-5156 |
| conjugated estrogens/ trimegestone | Wyeth Pharmaceuticals Collegeville, PA | postmenopausal osteoporosis (see also obstetric/gynecologic) | Phase III (800) 934-5556 |
| CP-195543 | Pfizer New York, NY | rheumatoid arthritis | Phase II (860) 732-5156 |
| CP-481715 | Pfizer New York, NY | rheumatoid arthritis | Phase I (860) 732-5156 |
| CP-690550 | Pfizer New York, NY | rheumatoid arthritis | Phase II (860) 732-5156 |
| CP-751871 | Pfizer New York, NY | rheumatoid arthritis | Phase I (860) 732-5156 |
| CYT-424 | Cytogen Princeton, NJ | rheumatoid arthritis | Phase I (800) 833-3533 |

ARTHRITIS/MUSCULOSKELETAL DISORDERS

| Product Name | Company | Indication | Development Status |
|------------------------------------|--|--|---|
| denosumab | Amgen <i>Thousand Oaks, CA</i> | osteoporosis, postmenopausal osteoporosis | Phase III (805) 447-1000 |
| | | bone loss induced by hormone ablation therapy for breast cancer | Phase III (805) 447-1000 |
| | | rheumatoid arthritis | Phase II (805) 447-1000 |
| Dentonin™ AC 100 | Acologix <i>Hayward, CA</i> | postmenopausal osteoporosis | Phase I (510) 512-7200 |
| doramapimod | Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> | rheumatoid arthritis (see also autoimmune) | Phase II (800) 243-0127 |
| efipladib | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | osteoarthritis, rheumatoid arthritis | Phase II (800) 934-5556 |
| ERB-041 | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | rheumatoid arthritis (see also obstetric/gynecologic) | Phase II (800) 934-5556 |
| estradiol/progestin transdermal | Watson Pharmaceuticals <i>Corona, CA</i> | postmenopausal osteoporosis (see also obstetric/gynecologic) | application submitted (800) 249-5499 |
| estradiol transdermal | Elan Pharmaceutical <i>New York, NY</i> | postmenopausal osteoporosis (see also obstetric/gynecologic) | Phase III (212) 407-5740 |
| estradiol/ trimegestone | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | postmenopausal osteoporosis (see also obstetric/gynecologic) | Phase III (800) 934-5556 |
| Femara® letrozole | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | osteoporosis | Phase III (888) NOW-NOVA |
| fentanyl patch | ZARS <i>Salt Lake City, UT</i> | osteoarthritis | Phase II (801) 350-0202 |
| Fludara® fludarabine | Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> | rheumatoid arthritis (see also autoimmune) | Phase II (888) 84-BAYER |
| golimumab | Centocor <i>Horsham, PA</i> Schering-Plough <i>Kenilworth, NJ</i> | rheumatoid arthritis (see also lung/respiratory) | Phase III (610) 651-6000 (908) 298-4000 |
| Humira® adalimumab | Abbott Laboratories <i>Abbott Park, IL</i> | juvenile rheumatoid arthritis (see also autoimmune) | application submitted (847) 937-6100 |
| ibuprofen-phospha- tidylcholine | PLx Pharma <i>Houston, TX</i> | osteoarthritis | Phase II (713) 842-1249 |
| icatibant (HOE 140) | sanofi-aventis <i>Bridgewater, NJ</i> | osteoarthritis pain | Phase II (800) 633-1610 |
| IL-1 receptor type-2 | Amgen <i>Thousand Oaks, CA</i> | rheumatoid arthritis | Phase I (805) 447-1000 |
| immune globulin | Protein Therapeutics <i>Tucson, AZ</i> | juvenile rheumatoid arthritis, rheumatoid arthritis | Phase II (520) 574-1632 |

ARTHRITIS/MUSCULOSKELETAL DISORDERS

| Product Name | Company | Indication | Development Status |
|--|--|---|---|
| INCB-3284 | Incyte <i>Wilmington, DE</i> | rheumatoid arthritis | Phase II (302) 498-6700 |
| KB-002 | KaloBios Pharmaceuticals <i>Palo Alto, CA</i> | rheumatoid arthritis | Phase I (650) 843-1897 |
| ketoprofen patch | ZARS <i>Salt Lake City, UT</i> | osteoarthritis | Phase III (801) 350-0202 |
| Kineret® anakinra | Amgen <i>Thousand Oaks, CA</i> | juvenile rheumatoid arthritis, osteoarthritis (see also lung/respiratory) | Phase II (805) 447-1000 |
| L-873724 | Merck <i>Whitehouse Station, NJ</i> | postmenopausal osteoporosis | Phase I (800) 672-6372 |
| LAS-34475 | Almirall-Prodesfarma <i>Barcelona, Spain</i> | osteoarthritis | Phase II |
| LGD-2941 | Ligand Pharmaceuticals <i>San Diego, CA</i> TAP Pharmaceutical Products <i>Lake Forest, IL</i> | osteoporosis | Phase I (858) 550-7500 (847) 582-2000 |
| lymphotoxin-beta receptor | Biogen Idec <i>Cambridge, MA</i> | rheumatoid arthritis | Phase I (617) 679-2000 |
| maraviroc | Pfizer <i>New York, NY</i> | rheumatoid arthritis | Phase II (860) 732-5156 |
| Miacalcin® Nasal Spray calcitonin-salmon | Novartis Pharmaceuticals <i>East Hanover, NJ</i> Noven Pharmaceuticals <i>Miami, FL</i> | prevention of vertebral fractures in postmenopausal women | application submitted (888) NOW-NOVA (305) 253-5099 |
| MK-0812 | Merck <i>Whitehouse Station, NJ</i> | rheumatoid arthritis (see also autoimmune) | Phase II (800) 672-6372 |
| MK-0822 | Merck <i>Whitehouse Station, NJ</i> | osteoarthritis, postmenopausal osteoporosis | Phase II (800) 672-6372 |
| MM-093 (recombinant human alpha-fetoprotein) | Merrimack Pharmaceuticals <i>Cambridge, MA</i> | rheumatoid arthritis (see also autoimmune) | Phase I (617) 441-1000 |
| naproxinod | NicOx <i>Sophia Antipolis, France</i> | osteoarthritis | Phase III www.nicox.com |
| Neoral® ciclosporin | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | juvenile rheumatoid arthritis | application submitted (888) NOW-NOVA |
| Neumega® oprelvekin | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | rheumatoid arthritis | Phase II (800) 934-5556 |
| Nipent® pentostatin | Mayne Pharma (Hospira) <i>Lake Forest, IL</i> | rheumatoid arthritis | Phase II (224) 212-2000 |

ARTHRITIS/MUSCULOSKELETAL DISORDERS

| Product Name | Company | Indication | Development Status |
|---|---|--|---|
| ocrelizumab (anti-CD20 MAb) | Biogen Idec Cambridge, MA Genentech South San Francisco, CA | rheumatoid arthritis | Phase III (617) 679-2000 (650) 225-1000 |
| ofatumumab (HuMax-CD20) | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | rheumatoid arthritis | Phase II (888) 825-5249 |
| Oporia™ lasofoxifene | Ligand Pharmaceuticals San Diego, CA Pfizer New York, NY | postmenopausal osteoporosis prevention (see also cancer, obstetric/gynecologic) | application submitted (858) 550-7500 (860) 732-5156 |
| | | postmenopausal osteoporosis treatment | Phase III (858) 550-7500 (860) 732-5156 |
| oral salmon calcitonin using eligen® technology | Emisphere Technologies Tarrytown, NY Novartis Pharmaceuticals East Hanover, NJ | osteoarthritis, postmenopausal osteoporosis | Phase III (914) 347-2220 (888) NOW-NOVA |
| p38 kinase inhibitor | Bristol-Myers Squibb Princeton, NJ | rheumatoid arthritis (see also autoimmune) | Phase I (212) 546-4000 |
| Paxceed™ micellar paclitaxel for injection | Angiotech Pharmaceuticals Vancouver, BC | rheumatoid arthritis (see also autoimmune) | Phase II (604) 221-7676 |
| PD-360324 | Pfizer New York, NY | rheumatoid arthritis | Phase I (860) 732-5156 |
| Pennsaid® diclofenac transdermal | Nuvo Research Markham, ON | osteoarthritis | application submitted (905) 415-1446 |
| Pennsaid® Plus diclofenac transdermal (second generation) | Nuvo Research Markham, ON | osteoarthritis | Phase II (905) 415-1446 |
| PF-755616 | Pfizer New York, NY | rheumatoid arthritis | Phase I (860) 732-5156 |
| PMI-001 | Phytomedics Jamesburg, NJ | rheumatoid arthritis (see also autoimmune) | Phase II (609) 655-0715 |
| PN-100 | POZEN Chapel Hill, NC | osteoarthritis | Phase II (919) 913-1030 |
| PN-200 | POZEN Chapel Hill, NC | osteoarthritis, rheumatoid arthritis | Phase II (919) 913-1030 |
| PN-400 | AstraZeneca Wilmington, DE POZEN Chapel Hill, NC | signs and symptoms of osteoarthritis and rheumatoid arthritis | Phase II (800) 236-9933 (919) 913-1030 |
| pralnacasan (VX-702) | Vertex Pharmaceuticals Cambridge, MA | osteoporosis, rheumatoid arthritis | Phase II (617) 444-6777 |

ARTHRITIS/MUSCULOSKELETAL DISORDERS

| Product Name | Company | Indication | Development Status |
|--|---|---|---|
| PREOS® parathyroid hormone (rDNA origin) for injection | NPS Pharmaceuticals <i>Salt Lake City, UT</i> | postmenopausal osteoporosis | application submitted (801) 583-4939 |
| Prexige® lumiracoxib | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | osteoarthritis, rheumatoid arthritis (see also obstetric/gynecologic) | Phase III (888) NOW-NOVA |
| PRTX-100 | Protalex <i>New Hope, PA</i> | rheumatoid arthritis (see also autoimmune) | Phase I (215) 862-9720 |
| PTH-131A | Unigene Laboratories <i>Fairfield, NJ</i> | osteoporosis | Phase I (973) 882-0860 |
| R-788 | Rigel Pharmaceuticals <i>South San Francisco, CA</i> | rheumatoid arthritis (see also autoimmune) | Phase II (650) 624-1100 |
| R1503 (kinase inhibitor) | Roche <i>Nutley, NJ</i> | rheumatoid arthritis | Phase II (973) 235-5000 |
| relacatib (cathepsin K inhibitor) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> Human Genome Sciences <i>Rockville, MD</i> | osteoarthritis, postmenopausal osteoporosis | Phase I (888) 825-5249 (301) 309-8504 |
| Remicade® infliximab | Centocor <i>Horsham, PA</i> | juvenile rheumatoid arthritis (see also autoimmune, lung/respiratory) | Phase III (610) 651-6000 |
| rilonacept (IL-1 trap) | Regeneron Pharmaceuticals <i>Tarrytown, NY</i> | juvenile rheumatoid arthritis (see also autoimmune) | Phase II (914) 345-7400 |
| Rituxan® rituximab | Genentech <i>South San Francisco, CA</i> | rheumatoid arthritis (DMARD inadequate responders) (see also autoimmune, kidney/urologic) | Phase III (650) 225-1000 |
| RN624 | Rinat Neuroscience <i>South San Francisco, CA</i> | osteoarthritis | Phase II (650) 615-7300 |
| Rocaltrol® calcitrol | Roche <i>Nutley, NJ</i> | postmenopausal osteoporosis | Phase III (973) 235-5000 |
| SAR 479746 (MLN0415) | Millennium Pharmaceuticals <i>Cambridge, MA</i> sanofi-aventis <i>Bridgewater, NJ</i> | arthritis | Phase I (800) 390-5663 (800) 633-1610 |
| SC-84250 | Pfizer <i>New York, NY</i> | osteoarthritis | Phase II (860) 732-5156 |
| SCIO-323 | Scios <i>Mountain View, CA</i> | rheumatoid arthritis | Phase I (650) 564-5000 |
| SCIO-469 | Scios <i>Mountain View, CA</i> | rheumatoid arthritis | Phase II (650) 564-5000 |

ARTHRITIS/MUSCULOSKELETAL DISORDERS

| Product Name | Company | Indication | Development Status |
|---|--|--|---|
| SIM-688 | ArQule Woburn, MA Wyeth Pharmaceuticals Collegeville, PA | rheumatoid arthritis | Phase I (781) 994-0300 (800) 934-5556 |
| Synvisc® (second generation) | Genzyme Cambridge, MA | osteoarthritis | Phase III (888) 379-6847 |
| teriparatide intranasal | Nastech Pharmaceutical Bothell, WA Procter & Gamble Pharmaceuticals Cincinnati, OH | osteoporosis | Phase II (425) 908-3600 |
| teriparatide oral (PTH 3-34) | Emisphere Technologies Tarrytown, NY Novartis Pharmaceuticals East Hanover, NJ | postmenopausal osteoporosis | Phase I (914) 347-2220 (888) NOW-NOVA |
| tgAAC94 | Targeted Genetics Seattle, WA | rheumatoid arthritis | Phase I (206) 623-7612 |
| Thalomid® thalidomide | Celgene Summit, NJ | rheumatoid arthritis (see also autoimmune, cancer) | Phase II (908) 673-9000 |
| Torisel™ temsirolimus | Wyeth Pharmaceuticals Collegeville, PA | rheumatoid arthritis (see also autoimmune) | Phase II (800) 934-5556 |
| TRU-015 | Trubion Pharmaceuticals Seattle, WA Wyeth Pharmaceuticals Collegeville, PA | rheumatoid arthritis | Phase II (206) 838-0500 (800) 934-5556 |
| Vicodin® CR hydrocodone/ acetaminophen controlled-release | Abbott Laboratories Abbott Park, IL | osteoarthritis | Phase III (847) 937-6100 |
| Viviant™ bazedoxifene | Ligand Pharmaceuticals San Diego, CA Wyeth Pharmaceuticals Collegeville, PA | postmenopausal osteoporosis prevention | application submitted (858) 550-7500 (800) 934-5556 |
| | | postmenopausal osteoporosis treatment | Phase III (858) 550-7500 (800) 934-5556 |
| WAY-195725 | Wyeth Pharmaceuticals Collegeville, PA | osteoarthritis, rheumatoid arthritis (see also obstetric/gynecologic) | Phase I (800) 934-5556 |
| zoledronic acid | Novartis Pharmaceuticals East Hanover, NJ | postmenopausal osteoporosis treatment | application submitted (888) NOW-NOVA |
| | | osteoporosis prevention | Phase III (888) NOW-NOVA |
| | | rheumatoid arthritis | Phase II (888) NOW-NOVA |

AUTOIMMUNE DISEASES

| Product Name | Company | Indication | Development Status |
|---|---|--|---|
| <i>Where to find additional autoimmune diseases—medicines in development for rheumatoid arthritis are listed under Arthritis/Musculoskeletal Disorders; medicines for diabetes are listed under Diabetes.</i> | | | |
| 683699 (dual alpha4 integrin antagonist) | GlaxoSmithKline Philadelphia, PA <i>Rsch. Triangle Park, NC</i> | multiple sclerosis | Phase II (888) 825-5249 |
| ABT-325 | Abbott Laboratories Abbott Park, IL | autoimmune diseases | Phase I (847) 937-6100 |
| ABT-874 | Abbott Laboratories Abbott Park, IL | psoriasis | Phase II (847) 937-6100 |
| Actemra™ tocilizumab | Roche Nutley, NJ | systemic lupus erythematosus (see also arthritis/musculoskeletal) | Phase I (973) 235-5000 |
| Actos® pioglitazone | Eli Lilly Indianapolis, IN Takeda Pharmaceuticals North America Deerfield, IL | multiple sclerosis | Phase I (317) 276-2000 (224) 554-6500 |
| AGN-194310 | Allergan Irvine, CA | psoriasis | Phase III (714) 246-4500 |
| Alferon N Injection® interferon-alpha-n3 | Hemispherx Biopharma Philadelphia, PA | multiple sclerosis | Phase II (215) 988-0080 |
| Amevive® alefacept | Biogen Idec Cambridge, MA | scleroderma (see also arthritis/musculoskeletal) | in clinical trials (617) 679-2000 |
| AMG 531 | Amgen Thousand Oaks, CA | immune thrombocytopenic purpura | Phase III (805) 447-1000 |
| AMG 623 | Amgen Thousand Oaks, CA | systemic lupus erythematosus | Phase I (805) 447-1000 |
| AMG 714 | Amgen Thousand Oaks, CA | psoriasis (see also arthritis/musculoskeletal) | Phase I (805) 447-1000 |
| Ampligen® | Hemispherx Biopharma Philadelphia, PA | chronic fatigue syndrome | Phase III (215) 988-0080 |
| AN-0128 | Anacor Pharmaceuticals Palo Alto, CA | psoriasis | Phase I (650) 739-0700 |
| androgen CPE215 therapy | Bentley Pharmaceuticals Exeter, PA | fibromyalgia | in clinical trials (603) 658-6100 |
| anti-interferon alpha | Genentech South San Francisco, CA | systemic lupus erythematosus | Phase I (650) 225-1000 |
| anti-interferon gamma, polyclonal antibody | Advanced Biotherapy Chicago, IL | psoriasis | in clinical trials (312) 427-1912 |
| antineoplaston AS2 1 (oral) | Burzynski Research Institute Houston, TX | autoimmune disorders (see also cancer) | Phase II |

AUTOIMMUNE DISEASES

| Product Name | Company | Indication | Development Status |
|--------------------------------|--|--|---|
| Asord™ becocalcidiol | CollaGenex Pharmaceuticals Newton, PA QuatRx Pharmaceuticals Ann Arbor, MI | psoriasis | Phase II (215) 579-7388 |
| atacept | EMD Serono Rockland, MA ZymoGenetics Seattle, WA | systemic lupus erythematosus (see also arthritis/musculoskeletal) | Phase I (800) 283-8088 (800) 775-6686 |
| AVE9897 (MLN3897) | Millennium Pharmaceuticals Cambridge, MA sanofi-aventis Bridgewater, NJ | multiple sclerosis (see also arthritis/musculoskeletal) | Phase I (800) 390-5663 (800) 633-1610 |
| azathioprine oral solution | DOR BioPharma Miami, FL | autoimmune disorders | Phase II (786) 425-3848 |
| BCX 4208 (R-3421) | BioCryst Pharmaceuticals Birmingham, AL Roche Nutley, NJ | autoimmune disorders, psoriasis | Phase I (205) 444-4600 (973) 235-5000 |
| belimumab | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC Human Genome Sciences Rockville, MD | systemic lupus erythematosus (see also arthritis/musculoskeletal) | Phase III (888) 825-5249 (301) 309-8504 |
| BG-12/oral fumarate | Biogen Idec Cambridge, MA | multiple sclerosis | Phase III (617) 679-2000 |
| BHT-3009 | Bayhill Therapeutics Palo Alto, CA | multiple sclerosis | Phase II (650) 320-2800 |
| BIO 023 | Gardant Pharmaceuticals New York, NY | psoriasis | Phase I (212) 332-4387 |
| BR3-Fc | Biogen Idec Cambridge, MA Genentech South San Francisco, CA | Sjogren's syndrome (see also arthritis/musculoskeletal) | Phase II (617) 679-2000 (650) 225-1000 |
| Campath® alemtuzumab | Bayer HealthCare Pharmaceuticals Wayne, NJ | multiple sclerosis | Phase II (888) 84-BAYER |
| CC-10004 | Celgene Summit, NJ | psoriasis | Phase II (908) 673-9000 |
| CCX-915 | ChemoCentryx Mountain View, CA | multiple sclerosis | Phase I (650) 210-2900 |
| CH-1504 | Chelsea Therapeutics Charlotte, NC | psoriasis (see also arthritis/musculoskeletal) | Phase I (704) 341-1516 |
| ciclosporin | Cellgate Redwood City, CA | psoriasis | Phase II (650) 610-7800 |

AUTOIMMUNE DISEASES

| Product Name | Company | Indication | Development Status |
|--|--|--|---|
| CNTO 1275 | Centocor <i>Horsham, PA</i> | psoriasis | Phase III (610) 651-6000 |
| | Medarex <i>Princeton, NJ</i> | multiple sclerosis | Phase II (610) 651-6000 |
| Copaxone® glatiramer acetate (oral) | Teva Pharmaceuticals North America <i>North Wales, PA</i> | relapsing-remitting multiple sclerosis | Phase III (215) 591-3000 |
| CTA 018 | Cytochroma <i>Markham, ON</i> | psoriasis | Phase II (905) 479-5306 |
| cyclobenzaprine | Vela Pharmaceuticals <i>Ewing, NJ</i> | fibromyalgia | Phase II (609) 771-8660 |
| Cymbalta® duloxetine | Eli Lilly <i>Indianapolis, IN</i> | fibromyalgia | Phase III (317) 276-2000 |
| | | chronic fatigue syndrome | Phase II (317) 276-2000 |
| doramapimod | Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> | psoriasis (see also arthritis/musculoskeletal) | Phase II (203) 798-9988 |
| E2007 | Eisai <i>Ridgefield Park, NJ</i> | multiple sclerosis (see also neurologic) | Phase II (888) 274-2378 |
| edratide | Teva Pharmaceuticals North America <i>North Wales, PA</i> | systemic lupus erythematosus | Phase II (215) 591-3000 |
| epratuzumab | Immunomedics <i>Morris Plains, NJ</i> | systemic lupus erythematosus | Phase III (973) 605-8200 |
| ETI-201 | Elusys Therapeutics <i>Pine Brook, NJ</i> | systemic lupus erythematosus | Phase I (973) 808-0222 |
| fingolimod | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | multiple sclerosis | Phase III (888) NOW-NOVA |
| Fludara® fludarabine | Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> | multiple sclerosis (see also arthritis/musculoskeletal) | Phase II (888) 84-BAYER |
| Gamunex® immune globulin | Talecris Biotherapeutics <i>Rsch. Triangle Park, NC</i> | multiple sclerosis | Phase II (919) 316-6300 |
| Humira® adalimumab | Abbott Laboratories <i>Abbott Park, IL</i> | psoriasis (see also arthritis/musculoskeletal) | application submitted (847) 937-6100 |
| ibutamoren (MK-0677) | Merck <i>Whitehouse Station, NJ</i> | fibromyalgia | Phase II (800) 672-6372 |
| inecalcitol | Hybrigenics <i>Cambridge, MA</i> | psoriasis | Phase II (617) 583-1350 |
| lacosamide | Schwarz Pharma <i>Mequon, WI</i> | fibromyalgia (see also neurologic) | Phase II (262) 238-5400 |

AUTOIMMUNE DISEASES

| Product Name | Company | Indication | Development Status |
|---|--|--|---|
| Leukine® sargramostim | Bayer HealthCare Pharmaceuticals Wayne, NJ | multiple sclerosis | Phase I (888) 842-2937 |
| Leustatin® cladribine | Johnson & Johnson Pharmaceutical Research & Development Raritan, NJ | multiple sclerosis | Phase III (800) 817-5286 |
| Levulan® PD aminolevulinic acid | DUSA Pharmaceuticals Wilmington, MA | psoriasis (see also cancer) | in clinical trials (978) 657-7500 |
| LIF-313 | Enhance Lifesciences New York, NY | psoriasis | Phase I |
| MBP-8298 | BioMS Medical Edmonton, AB | multiple sclerosis | Phase III (780) 413-7152 |
| MEDI-545 | Medarex Princeton, NJ MedImmune Gaithersburg, MD | psoriasis, systemic lupus erythematosus | Phase I (609) 430-2880 (301) 298-0000 |
| milnacipran | Cypress Biosciences San Diego, CA Forest Laboratories New York, NY | fibromyalgia (see also psychiatric) | Phase III (858) 452-2323 (800) 947-5227 |
| mitoxantrone (liposome encapsulated) | NeoPharm Waukegan, IL | multiple sclerosis | Phase I (847) 887-0800 |
| MK-0812 | Merck Whitehouse Station, NJ | multiple sclerosis (see also arthritis/musculoskeletal) | Phase II (800) 672-6372 |
| MM-093 (recombinant human alpha- fetoprotein) | Merrimack Pharmaceuticals Cambridge, MA | psoriasis (see also arthritis/musculoskeletal) | Phase II (617) 441-1000 |
| MV-9411 | Miravant Medical Technologies Santa Barbara, CA | psoriasis | Phase II (888) 768-5501 |
| Neurelan® fampridine-SR | Acorda Therapeutics Hawthorne, NY | multiple sclerosis | Phase III (914) 347-4300 |
| NeuroVax™ | Orchestra Therapeutics Carlsbad, CA | multiple sclerosis | Phase II (760) 431-7080 |
| Orencia® abatacept | Bristol-Myers Squibb Princeton, NJ | autoimmune diseases | Phase II (212) 546-4000 |
| P38 kinase inhibitor | Bristol-Myers Squibb Princeton, NJ | psoriasis (see also arthritis/musculoskeletal) | Phase I (212) 546-4000 |
| Paxceed™ micellar paclitaxel for injection | Angiotech Pharmaceuticals Vancouver, BC | severe psoriasis (see also arthritis/musculoskeletal) | Phase II (604) 221-7676 |

AUTOIMMUNE DISEASES

| Product Name | Company | Indication | Development Status |
|--|--|--|---|
| Paxil® paroxetine | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | fibromyalgia (see also gastrointestinal) | Phase III (888) 825-5249 |
| PEG-Intron® peginterferon alfa-2b | Schering-Plough Kenilworth, NJ | multiple sclerosis | Phase II (908) 298-4000 |
| PF-738502 | Pfizer New York, NY | fibromyalgia | Phase I (860) 732-5156 |
| PI-0824 | Peptimmune Cambridge, MA | pemphigus vulgaris | Phase I (617) 705-8000 |
| PMI-001 | Phytomedics Jamesburg, NJ | autoimmune disorders (see also arthritis/musculoskeletal) | in clinical trials (609) 655-0715 |
| Prestara™ prasferone | Genelabs Technologies Redwood City, CA | systemic lupus erythematosus | Phase III (650) 369-9500 |
| Pristiq™ descenlafaxine | Wyeth Pharmaceuticals Collegeville, PA | fibromyalgia (see also obstetric/gynecologic, psychiatric) | Phase III (800) 934-5556 |
| Promacta™ eltrombopag | Ligand Pharmaceuticals San Diego, CA | idiopathic thrombocytopenic purpura | Phase III (858) 550-7500 |
| Provecta™ | Provectus Pharmaceuticals Knoxville, TN | psoriasis | Phase I (865) 769-4011 |
| PRTX-100 | Protalex New Hope, PA | autoimmune disorders (see also arthritis/musculoskeletal) | Phase I (215) 862-9720 |
| Psoraxine® psoriasis vaccine | Astralis Fairfield, NJ Pacira Pharmaceuticals San Diego, CA | psoriasis | Phase II (973) 227-7168 (858) 625-2414 |
| R-788 | Rigel Pharmaceuticals South San Francisco, CA | immune thrombocytopenic purpura (see also arthritis/musculoskeletal) | Phase II (650) 624-1100 |
| Remicade® infliximab | Centocor Horsham, PA | sarcoidosis (see also arthritis/musculoskeletal, lung/respiratory) | Phase II (610) 651-6000 |
| RG-2077 | Repligen Waltham, MA | multiple sclerosis | Phase I (800) 622-2259 |
| rilonacept (IL-1 trap) | Regeneron Pharmaceuticals Tarrytown, NY | polymyalgia rheumatica (see also arthritis/musculoskeletal) | Phase II (914) 345-7400 |
| Rituxan® rituximab | Biogen Idec Cambridge, MA Genentech South San Francisco, CA | primary progressive multiple sclerosis, systemic lupus erythematosus (see also arthritis/musculoskeletal, kidney/urologic) | Phase III (617) 679-2000 (650) 225-1000 |
| | | immune thrombocytopenic purpura | Phase II (617) 679-2000 (650) 225-1000 |

AUTOIMMUNE DISEASES

| Product Name | Company | Indication | Development Status |
|--|--|---|--------------------------------------|
| RPI-78M | ReceptoPharm <i>Plantation, FL</i> | multiple sclerosis | Phase I (954) 321-8988 |
| RTA-403 (synthetic triterpenoids) | Reata Pharmaceuticals <i>Irving, TX</i> | autoimmune disorders | Phase I (972) 865-2219 |
| sym-001 | Symphogen <i>Lyngby, Denmark</i> | idiopathic thrombocytopenic purpura | Phase I www.symphogen.com |
| tacrolimus | Astellas Pharma US <i>Deerfield, IL</i> | psoriasis (see also lung/respiratory) | Phase III (800) 695-4321 |
| Targretin® Capsules bexarotene oral | Ligand Pharmaceuticals <i>San Diego, CA</i> | psoriasis (see also cancer) | Phase II (858) 550-7500 |
| Targretin® Gel bexarotene topical | Ligand Pharmaceuticals <i>San Diego, CA</i> | psoriasis | Phase II (858) 550-7500 |
| Tauferon™ interferon-tau | Pepgen <i>Alameda, CA</i> | multiple sclerosis | Phase II (510) 473-0010 |
| TBC-4746 | Encysive Pharmaceuticals <i>Houston, TX</i> | multiple sclerosis (see also lung/respiratory) | Phase I (713) 796-8822 |
| Tempostatin™ halofuginone | Collgard Biopharmaceuticals <i>Atlanta, GA</i> | scleroderma | in clinical trials |
| teplizumab | MacroGenics <i>Rockville, MD</i> | multiple sclerosis (see also diabetes) | Phase I (301) 251-5172 |
| teriflunomide (HMR1726) | sanofi-aventis <i>Bridgewater, NJ</i> | multiple sclerosis (monotherapy) | Phase III (800) 633-1610 |
| Thalomid® thalidomide | Celgene <i>Summit, NJ</i> | systemic lupus erythematosus (see also arthritis/musculoskeletal, cancer) | in clinical trials (908) 673-9000 |
| Torisel™ temsirolimus | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | multiple sclerosis (see also arthritis/musculoskeletal) | Phase II (800) 934-5556 |
| Tovaxin™ multiple sclerosis vaccine | Opexa Therapeutics <i>The Woodlands, TX</i> | multiple sclerosis | Phase II (281) 272-9331 |
| TRX1 (anti-CD4 MAb) | TolerRx <i>Cambridge, MA</i> | cutaneous lupus erythematosus | Phase I (617) 354-8100 |
| TRX4 (anti-CD3 MAb) | TolerRx <i>Cambridge, MA</i> | psoriasis (see also diabetes) | Phase I (617) 354-8100 |
| valategrast (R-411) | Roche <i>Nutley, NJ</i> | multiple sclerosis | Phase I (973) 235-5000 |
| Valcyte® valganciclovir | Roche <i>Nutley, NJ</i> | chronic fatigue syndrome | Phase I (973) 235-5000 |
| Veldona® interferon-alpha lozenge | Amarillo Biosciences <i>Amarillo, TX</i> | Sjogren's syndrome (see also obstetric/gynecologic) | Phase III (806) 376-1741 |
| | | fibromyalgia | Phase II (806) 376-1741 |

AUTOIMMUNE DISEASES

| Product Name | Company | Indication | Development Status |
|---|--|---|--|
| VTP-201227 | Vitae Pharmaceuticals <i>Fort Washington, PA</i> | psoriasis | Phase II (215) 461-2000 |
| VX-765 | Vertex Pharmaceuticals <i>Cambridge, MA</i> | psoriasis | Phase II (617) 444-6777 |
| Zenapax [®] daclizumab | Biogen Idec <i>Cambridge, MA</i> PDL BioPharma <i>Fremont, CA</i> | multiple sclerosis (see also lung/respiratory) | Phase II (617) 679-2000 (510) 574-1400 |
| Zenvia [™] (AVP 923) | Avanir Pharmaceuticals <i>San Diego, CA</i> | pathological laughing or crying associated with multiple sclerosis (emotional lability or pseudobulbar effect) | application submitted (858) 622-5200 |
| Zocor [®] simvastatin | Merck <i>Whitehouse Station, NJ</i> | multiple sclerosis | in clinical trials (800) 672-6372 |
| Zyrem [®] sodium oxybate | Jazz Pharmaceuticals <i>Palo Alto, CA</i> | fibromyalgia | Phase III (650) 496-3777 |

CANCER

| Product Name | Company | Indication | Development Status |
|--|---|------------------------------------|---|
| A-007 | Tigris Pharmaceuticals <i>Bonita Springs, FL</i> | cervical intraepithelial neoplasia | Phase II (239) 444-5400 |
| A6 | Angstrom Pharmaceuticals <i>Solana Beach, CA</i> | ovarian ----- gynecological | Phase II (858) 350-1760 Phase I (858) 350-1760 |
| abagovomab | Menarini <i>Florence, Italy</i> | ovarian | Phase II www.menarini.com |
| ABI-007 | Abraxis BioScience <i>Los Angeles, CA</i> AstraZeneca <i>Wilmington, DE</i> | cervical, ovarian | Phase I (310) 883-1300 (800) 236-9933 |
| ABT-751 | Abbott Laboratories <i>Abbott Park, IL</i> | breast | Phase II (847) 937-6100 |
| AE37 | Antigen Express <i>Worcester, MA</i> | breast | Phase II (508) 852-8783 |
| aflibercept (VEGF-trap) | Regeneron Pharmaceuticals <i>Tarrytown, NY</i> sanofi-aventis <i>Bridgewater, NJ</i> | breast, ovarian | Phase II (914) 345-7400 (800) 633-1610 |
| Alimta [®] pemetrexed | Eli Lilly <i>Indianapolis, IN</i> | breast, ovarian | Phase II (800) 545-5979 |
| amolmogene (ZYC101a) | MGI Pharma <i>Bloomington, MN</i> | cervical dysplasia | Phase II (952) 346-4700 |

CANCER

| Product Name | Company | Indication | Development Status |
|---|---|--|--|
| amonafile | ChemGenex Pharmaceuticals <i>Menlo Park, CA</i> | breast, ovarian | Phase II (650) 474-9800 |
| Amplimexon® imexon | AmpliMed <i>Tucson, AZ</i> | breast | Phase I (520) 529-1000 |
| antineoplaston AS21 (oral) | Burzynski Research Institute <i>Houston, TX</i> | breast (see also autoimmune) | Phase II (713) 335-5697 |
| anti-PEM MAb | Somanta Pharmaceuticals <i>Irvine, CA</i> | breast | Phase I (949) 477-8090 |
| ANX-510 | Adventrx Pharmaceuticals <i>San Diego, CA</i> | breast | Phase II (858) 552-0866 |
| ANX-530 | Adventrx Pharmaceuticals <i>San Diego, CA</i> | breast | Phase I (858) 552-0866 |
| AP23573 | ARIAD Pharmaceuticals <i>Cambridge, MA</i> Merck <i>Whitehouse Station, NJ</i> | endometrial ----- breast, ovarian | Phase II (617) 494-0400 ----- Phase I (617) 494-0400 |
| Aromasin® exemestane | Pfizer <i>New York, NY</i> | breast cancer prevention | Phase III (860) 732-5156 |
| arzoxifene (next-generation SERM) | Eli Lilly <i>Indianapolis, IN</i> | breast cancer treatment (see also arthritis/musculoskeletal) ----- breast cancer prevention, endometrial, ovarian, peritoneal | Phase III (800) 545-5979 ----- Phase II (800) 545-5979 |
| AS-1402 (MAb) | Antisoma <i>London, England</i> | metastatic breast | Phase I |
| atamestane | Intarcia Therapeutics <i>Emeryville, CA</i> Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> | breast cancer | Phase III (510) 652-2600 (888) 84-BAYER |
| Avastin® bevacizumab | Genentech <i>South San Francisco, CA</i> | first-line metastatic breast ----- adjuvant breast, first-line metastatic ovarian, second-line metastatic breast, second-line metastatic ovarian ----- adjuvant HER2-negative breast, ovarian | Phase III completed (650) 225-1000 ----- Phase III (650) 225-1000 ----- Phase II (650) 225-1000 |
| axitinib | Pfizer <i>New York, NY</i> | breast | Phase I (860) 732-5156 |
| belinostat | CuraGen <i>Branford, CT</i> | ovarian | Phase II (888) 436-6642 |

CANCER

| Product Name | Company | Indication | Development Status |
|--|---|---|---|
| bleomycin (electrical pulse delivery) | Inovio Biomedical <i>San Diego, CA</i> | breast | Phase I (877) 4-INOVIO |
| bosutinib | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | breast | Phase II (800) 934-5556 |
| BZL-101 | United Biotech <i>Mountain View, CA</i> | breast, ovarian | Phase I (650) 961-9210 |
| CA4P (combrestatin) | OXIGENE <i>Waltham, MA</i> | breast, ovarian | Phase II (781) 547-5900 |
| Camptosar® irinotecan | Pfizer <i>New York, NY</i> | cervical | application submitted (860) 732-5156 |
| cancer vaccine | Genzyme <i>Cambridge, MA</i> | breast | Phase II (617) 252-7500 |
| canertinib | Pfizer <i>New York, NY</i> | ovarian | Phase II (860) 732-5156 |
| | | breast | Phase I (860) 732-5156 |
| CAT-5001 | Cambridge Antibody Technology <i>Palo Alto, CA</i> | ovarian | Phase I (650) 388-3300 |
| CDB-2914 | HRA Pharma <i>New York, NY</i> | uterine leiomyoma (see also obstetric/gynecologic) | Phase II (212) 679-2945 |
| CDX-1307 | Celldex Therapeutics <i>Phillipsburg, NJ</i> | breast | Phase I (908) 454-7120 |
| Celebrex® celecoxib | Pfizer <i>New York, NY</i> | cervical dysplasia | in clinical trials (860) 732-5156 |
| Corlux™ mifepristone | Corcept Therapeutics <i>Menlo Park, CA</i> | endometrial (see also neurologic, psychiatric) | Phase II (650) 327-3270 |
| | | uterine leiomyoma | in clinical trials (650) 327-3270 |
| DOXIL® doxorubicin | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> | breast | Phase III (800) 817-5286 |
| | | endometrial | in clinical trials (800) 817-5286 |
| E75 cancer vaccine | Aphera <i>Scottsdale, AZ</i> | breast | Phase II |
| EGEN-001 | Expression Genetics <i>Huntsville, AL</i> | ovarian | Phase I (256) 512-0077 |
| enzastaurin | Eli Lilly <i>Indianapolis, IN</i> | breast, ovarian | Phase II (800) 545-5979 |
| eribulin (E7389) | Eisai <i>Ridgefield Park, NJ</i> | breast | Phase III (888) 274-2378 |

CANCER

| Product Name | Company | Indication | Development Status |
|---|--|---|---|
| Evista® raloxifene | Eli Lilly <i>Indianapolis, IN</i> | breast cancer prevention, reduction of risk of breast cancer (see also obstetric/gynecologic) | application submitted (800) 545-5979 |
| exatecan | Daiichi Sankyo <i>Parsippany, NJ</i> | ovarian, peritoneal | Phase II (973) 359-2600 |
| formestane topical cream | Medical Discoveries <i>Salt Lake City, UT</i> | breast | in clinical trials (877) 633-4201 |
| Genasense® oblimersen sodium | Genta <i>Berkeley Heights, NJ</i> | breast | Phase II (908) 286-9800 |
| glufosfamide | Threshold Pharmaceuticals <i>Redwood City, CA</i> | breast, ovarian | Phase II (650) 474-8200 |
| GTI-2040 | Lorus Therapeutics <i>Toronto, ON</i> | breast | Phase II (416) 798-1200 |
| Herceptin® trastuzumab | Genentech <i>South San Francisco, CA</i> | ovarian | Phase II (650) 225-1000 |
| HKI-272 | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | breast | Phase II (800) 934-5556 |
| Hycamtin® topotecan | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | ovarian (first-line therapy) | Phase III (888) 825-5249 |
| idronoxil | Marshall Edwards <i>New York, NY</i> Novogen <i>New Canaan, CT</i> | ovarian | Phase III (203) 966-2556 |
| | | cervical, fallopian tube, vulvovaginal | Phase II (203) 966-2556 |
| indisulam (E7070) | Eisai <i>Ridgefield Park, NJ</i> | breast | Phase II (888) 274-2378 |
| INGN-225 (p53 vaccine) | Introgen Therapeutics <i>Austin, TX</i> | breast | Phase I (512) 708-9310 |
| IntraDose™ CDDP | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | breast | Phase III (888) NOW-NOVA |
| Iressa® gefitinib | AstraZeneca <i>Wilmington, DE</i> | breast | Phase II (800) 236-9933 |
| irofulven (MGI-114) | MGI Pharma <i>Bloomington, MN</i> | breast, ovarian | Phase II (800) 562-5580 |
| ispinesib | Cytokinetics <i>South San Francisco, CA</i> | breast | Phase II (650) 624-3000 |
| ixabepilone | Bristol-Myers Squibb <i>Princeton, NJ</i> | metastatic breast | application submitted (212) 546-4000 |
| larotaxel (XRP9881) | sanofi-aventis <i>Bridgewater, NJ</i> | breast | Phase III (800) 633-1610 |
| LeuProMaxx™ leuprorelin depot | Teva Parenteral Medicines <i>Irvine, CA</i> | uterine leiomyoma (see also obstetric/gynecologic) | Phase II (949) 455-4700 |

CANCER

| Product Name | Company | Indication | Development Status |
|--|--|---|--------------------------------------|
| Levulan® PD aminolevulinic acid | DUSA Pharmaceuticals <i>Wilmington, MA</i> | cervical intraepithelial neoplasia (see also autoimmune) | Phase II (978) 657-7500 |
| liposome encapsulated doxorubicin | NeoPharm <i>Waukegan, IL</i> | breast | Phase III (847) 887-0800 |
| LY-295501 | Genzyme Oncology <i>Cambridge, MA</i> | ovarian | Phase II (617) 761-8777 |
| LY-573636 | Eli Lilly <i>Indianapolis, IN</i> | fallopian tube, ovarian, peritoneal | Phase II (800) 545-5979 |
| Lymphoseek™ | Neoprobe <i>Dublin, OH</i> | breast | Phase II (800) 793-0079 |
| matuzumab | Takeda Pharmaceuticals North America <i>Deerfield, IL</i> | ovarian | Phase II (224) 554-6500 |
| milataxel | Taxolog <i>Fairfield, NJ</i> | breast | Phase II (866) TAXOLOG |
| MK-0752 | Merck <i>Whitehouse Station, NJ</i> | advanced breast (see also neurologic) | Phase I (800) 672-6372 |
| MKC-1 | EntreMed (Mikana) <i>Rockville, MD</i> | breast | Phase II (240) 864-2600 |
| Modrenal® trilostane | Bioenvision <i>New York, NY</i> | breast | in clinical trials (212) 750-6700 |
| MORAb-003 | Morphotek <i>Exton, PA</i> | ovarian | Phase II (610) 423-6100 |
| motesanib diphosphate (AMG 706) | Amgen <i>Thousand Oaks, CA</i> | first-line breast | Phase II (805) 447-1000 |
| MUC-1 cancer vaccine | Avantogen <i>Los Angeles, CA</i> | breast | Phase I (310) 552-2001 |
| Multikine® leukocyte interleukin injection | CEL-SCI <i>Vienna, VA</i> | cervical, cervical dysplasia | Phase II (703) 506-9460 |
| MVA-BN®-HER2 (vaccine) | BN ImmunoTherapeutics <i>Mountain View, CA</i> | breast | Phase I (650) 681-4660 |
| Myocet™ doxorubicin liposomal | Sopherion Therapeutics <i>Princeton, NJ</i> | breast | Phase III (609) 986-2021 |
| NBI-42902 | Neurocrine Biosciences <i>San Diego, CA</i> | breast, uterine leiomyoma (see also obstetric/gynecologic) | Phase I (858) 617-7600 |
| Neuvenge® lapuleucel-T | Dendreon <i>Seattle, WA</i> | breast, ovarian | Phase I (206) 256-4545 |
| NOV-002 | Novelos Therapeutics <i>Newton, MA</i> | breast, ovarian | Phase II (617) 244-1616 |

CANCER

| Product Name | Company | Indication | Development Status |
|--|---|--|---|
| oglufanide | Implicit Bioscience <i>Seattle, WA</i> | ovarian | in clinical trials (650) 851-3133 |
| Omnitarg™ pertuzumab | Genentech <i>South San Francisco, CA</i> | breast | Phase III (650) 225-1000 |
| | | ovarian | Phase II (650) 225-1000 |
| Oncolar® octreotide | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | breast | Phase III (888) NOW-NOVA |
| Oporia™ lasofoxifene | Ligand Pharmaceuticals <i>San Diego, CA</i> Pfizer <i>New York, NY</i> | breast cancer prevention (see also arthritis/musculoskeletal, obstetric/gynecologic) | Phase III (858) 550-7500 (860) 732-5156 |
| OPT-22 | Optimer Pharmaceuticals <i>San Diego, CA</i> | breast | Phase I (858) 909-0736 |
| Orathecin™ rubitecan | SuperGen <i>Dublin, CA</i> | breast, ovarian | Phase II (925) 560-0100 |
| OvaRex® oregovomab | Unither Pharmaceuticals <i>Wellesley Hills, MA</i> | ovarian | Phase III (781) 235-7412 |
| Panvac™-VF falimarev | Therion Biologics <i>Cambridge, MA</i> | ovarian | Phase II (617) 475-7500 |
| Panzem® NCD 2-methoxyestradiol | EntreMed <i>Rockville, MD</i> | ovarian | Phase II (240) 864-2600 |
| | | breast | Phase I (240) 864-2600 |
| patupilone | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | ovarian | Phase III (888) NOW-NOVA |
| | | breast | Phase II (888) NOW-NOVA |
| pazopanib | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | breast, cervical, fallopian tube, ovarian, peritoneal | Phase II (888) 825-5249 |
| pazopanib and Tykerb® lapatinib | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | breast | Phase II (888) 825-5249 |
| PD-325901 | Pfizer <i>New York, NY</i> | breast | Phase I (860) 732-5156 |
| perifosine (KRX-0401) | Keryx Biopharmaceuticals <i>New York, NY</i> | breast | Phase II (212) 531-5965 |
| PF-3512676 | Pfizer <i>New York, NY</i> | breast | Phase I (860) 732-5156 |
| Proellex™ | Repros Therapeutics <i>The Woodlands, TX</i> | uterine leiomyoma | Phase II (281) 719-3400 |

CANCER

| Product Name | Company | Indication | Development Status |
|---|---|--|--|
| PV-701 | Wellstat Biologics <i>Gaithersburg, MD</i> | cervical | Phase II (240) 631-2500 |
| R851 | Takeda Pharmaceuticals North America <i>Deerfield, IL</i> | cervical dysplasia (see also obstetric/gynecologic) | Phase II (224) 554-6500 |
| Recentim TM cediranib | AstraZeneca <i>Wilmington, DE</i> | breast | Phase II (800) 236-9933 |
| Removab [®] catumaxomab | Fresenius Biotech North America <i>Lexington, MA</i> | ovarian | Phase II (781) 482-6172 |
| rhizoxin | Astellas Pharma US <i>Deerfield, IL</i> | breast | Phase II (800) 727-7003 |
| Sarasar TM lonafarnib | Schering-Plough <i>Kenilworth, NJ</i> | breast | Phase II (908) 298-4000 |
| satraplatin | GPC Biotech <i>Waltham, MA</i> Spectrum Pharmaceuticals <i>Irvine, CA</i> | breast | Phase II (781) 890-9007 (949) 788-6700 |
| SNS-595 | Sunesis Pharmaceuticals <i>South San Francisco, CA</i> | ovarian | Phase II (650) 266-3500 |
| Sprycel TM dasatinib | Bristol-Myers Squibb <i>Princeton, NJ</i> | breast | Phase II (212) 546-4000 |
| SU-14813 | Pfizer <i>New York, NY</i> | breast | Phase II (860) 732-5256 |
| Sutent [®] sunitinib maleate | Pfizer <i>New York, NY</i> | breast | Phase III (860) 732-5156 |
| tacedinaline | Pfizer <i>New York, NY</i> | breast | Phase II (860) 732-5156 |
| TamoGel TM afimoxifene | ASCEND Therapeutics <i>Herndon, VA</i> | breast (see also obstetric/gynecologic) | Phase II (703) 471-4744 |
| tanespimycin (KOS-953) | Abbott Laboratories <i>Abbott Park, IL</i> | breast | Phase II (847) 937-6100 |
| Tarceva [®] erlotinib | Genentech <i>South San Francisco, CA</i> OSI Pharmaceuticals <i>Melville, NY</i> Roche <i>Nutley, NJ</i> | breast, ovarian | Phase II (800) 572-1932 |
| Targretin [®] Capsules bexarotene oral | Ligand Pharmaceuticals <i>San Diego, CA</i> | breast (see also autoimmune) | Phase II (858) 550-7500 |
| tariquidar | QLT <i>Vancouver, BC</i> | cervical, ovarian | Phase II (800) 663-5486 |
| TAS-108 | Taiho Pharma USA <i>Princeton, NJ</i> | breast | Phase II (609) 750-5300 |

CANCER

| Product Name | Company | Indication | Development Status |
|--|---|---|---|
| terameprocol (EM-1421) | Erimos Pharmaceuticals <i>Raleigh, NC</i> | cervical intraepithelial neoplasia | Phase II (919) 821-5204 |
| tesmilifene | YM Biosciences <i>Wayne, PA</i> | breast | Phase III (610) 560-0600 |
| testosterone progressive hydration vaginal tablet | Columbia Laboratories <i>Livingston, NJ</i> | uterine leiomyoma (see also obstetric/gynecologic) | Phase I (866) 566-5636 |
| Thalomid [®] thalidomide | Celgene <i>Summit, NJ</i> | breast (see also arthritis/musculoskeletal, autoimmune) | Phase II (908) 673-9000 |
| Thermodox [™] heat-activated liposomal encapsulated doxorubicin | Celsion <i>Columbia, MD</i> | breast | Phase I (410) 290-5390 |
| tirapazamine | SRI International <i>Menlo Park, CA</i> | cervical | Phase III (650) 859-2000 |
| Tocosol [®] paclitaxel | Sonus Pharmaceuticals <i>Bothell, WA</i> Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> | breast ----- ovarian | Phase III (425) 487-9500 (888) 84-BAYER Phase II (425) 487-9500 (888) 84-BAYER |
| trastuzumab-DM1 | Genentech <i>South San Francisco, CA</i> ImmunoGen <i>Cambridge, MA</i> | breast | Phase I (650) 225-1000 (617) 995-2500 |
| Trelstar Depot [®] triptorelin | Watson Pharmaceuticals <i>Corona, CA</i> | breast (see also obstetric/gynecologic) | Phase III (800) 249-5499 |
| Triapine [®] OCX 0191 | Vion Pharmaceuticals <i>New Haven, CT</i> | breast | Phase II (203) 498-4210 |
| Trisenox [™] arsenic trioxide | Cephalon <i>Frazer, PA</i> | breast, cervical | Phase II (610) 344-0200 |
| tucotuzumab celmoleukin | EMD Lexigen <i>Billerica, MA</i> | ovarian | Phase II (978) 294-1100 |
| Tykerb [®] lapatinib | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | refractory breast ----- breast (adjuvant therapy), breast (first-line therapy) | application submitted (888) 825-5249 Phase III (888) 825-5249 |
| verpasep caltespen (HspE7) vaccine | Nventa Biopharmaceuticals <i>San Diego, CA</i> Roche <i>Nutley, NJ</i> | cervical, cervical dysplasia (see also obstetric/gynecologic) | Phase II (858) 202-4900 (973) 235-5000 |

CANCER

| Product Name | Company | Indication | Development Status |
|---|---|---|--|
| vinflunine | Bristol-Myers Squibb <i>Princeton, NJ</i> Pierre Fabre Medicament <i>Paris, France</i> | breast | Phase III (212) 546-4000 |
| vinorelbine | Novacea <i>South San Francisco, CA</i> | advanced breast (oral), ovarian (intravenous) ----- cervical (intravenous) | Phase III (650) 228-1800 Phase II (650) 228-1800 |
| Xinlay™ atrasentan | Abbott Laboratories <i>Abbott Park, IL</i> | ovarian | Phase II (847) 937-6100 |
| Xorane™ oral paclitaxel | IVAX <i>Miami, FL</i> | breast | Phase II (305) 575-6000 |
| XRP6258 (taxoid, tubulin inhibitor) | sanofi-aventis <i>Bridgewater, NJ</i> | breast tumors | Phase II (800) 633-1610 |
| Xyotax™ polyglutamate paclitaxel | Cell Therapeutics <i>Seattle, WA</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i> | ovarian ----- peritoneal ----- fallopian tube | Phase III (800) 215-CELL (888) NOW-NOVA Phase II (800) 215-CELL (888) NOW-NOVA Phase I (800) 215-CELL (888) NOW-NOVA |
| Yondelis® trabectedin (Orphan Drug) | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> | relapsed ovarian ----- breast, endometrial | Phase III (800) 817-5286 Phase II (800) 817-5286 |
| Zactima® vandetanib | AstraZeneca <i>Wilmington, DE</i> | breast | Phase II (800) 236-9933 |
| ZK epothilone | Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> | breast ----- ovarian | Phase II (888) 84-BAYER Phase I (888) 84-BAYER |

DIABETES

| Product Name | Company | Indication | Development Status |
|---|--|-----------------|----------------------------|
| 189075 (sodium-dependent glucose transport [SGLT2] antagonist) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | type 2 diabetes | Phase II (888) 825-5249 |

DIABETES

| Product Name | Company | Indication | Development Status |
|---|--|----------------------------------|---|
| 376501 (PPAR gamma partial agonist) | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | type 2 diabetes | Phase I (888) 825-5249 |
| 625019 (PPAR pan agonist) | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | type 2 diabetes | Phase I (888) 825-5249 |
| 677954 (PPAR pan agonist) | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | type 2 diabetes | Phase II (888) 825-5249 |
| ABT-279 | Abbott Laboratories Abbott Park, IL | type 2 diabetes | Phase I (847) 937-6100 |
| Acomplia® rimonabant | sanofi-aventis Bridgewater, NJ | type 2 diabetes | Phase III (800) 633-1610 |
| AERx® iDMS insulin solution for inhalation (NN1998) | Aradigm Hayward, CA Novo Nordisk Princeton, NJ | type 1 diabetes, type 2 diabetes | Phase III (510) 265-9000 (800) 727-6500 |
| AI-401 | Autolmmune Pasadena, CA | type 1 diabetes prevention | Phase III (626) 792-1235 |
| AKP-111 | Akesis Pharmaceuticals San Diego, CA | type 2 diabetes | Phase I (858) 454-4311 |
| AKP-320 | Akesis Pharmaceuticals San Diego, CA | type 2 diabetes | in clinical trials (858) 454-4311 |
| albiglutide (716155) | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | type 2 diabetes | Phase II (888) 825-5249 |
| Albulin™ albumin/insulin | CoGenesys Rockville, MD | type 1 diabetes, type 2 diabetes | in clinical trials (240) 821-9000 |
| aleglitazar (R1439) | Roche Nutley, NJ | type 2 diabetes | Phase II (973) 235-5000 |
| alogliptin | Takeda Pharmaceuticals North America Deerfield, IL | type 2 diabetes | Phase III (224) 554-6500 |
| ALS 20426 | Alantos Pharmaceuticals Cambridge, MA | type 2 diabetes | Phase I (617) 577-0011 |
| Altace® ramipril | King Pharmaceuticals Bristol, TN | type 2 diabetes prevention | Phase III (800) 776-3637 |
| Alveair™ inhaled insulin | Coremed Lake Bluff, IL | diabetes | Phase I (847) 549-9098 |
| AMG 221 | Amgen Thousand Oaks, CA | type 2 diabetes | Phase I (800) 77-AMGEN |
| APD 668 | Arena Pharmaceuticals San Diego, CA Johnson & Johnson Pharmaceutical Research & Development Raritan, NJ | type 2 diabetes | Phase I (858) 453-7200 (800) 817-5286 |

DIABETES

| Product Name | Company | Indication | Development Status |
|--|---|---|--|
| Apidra® SoloStar® insulin glulisine | sanofi-aventis <i>Bridgewater, NJ</i> | type 2 diabetes | application submitted (800) 633-1610 |
| AT-1391 (daily insulin skin patch) | Altea Therapeutics <i>Tucker, GA</i> | type 1 diabetes, type 2 diabetes | Phase I (678) 495-3100 |
| Avandia® rosiglitazone | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | prevention of diabetes, prevention of disease progression (see also neurologic) | Phase III (888) 825-5249 |
| Avandia® rosiglitazone/ simvastatin | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | type 2 diabetes | Phase III (888) 825-5249 |
| AVE0010 (GLP1 agonist) | sanofi-aventis <i>Bridgewater, NJ</i> | type 2 diabetes | Phase II (800) 633-1610 |
| AVE0847 (PPAR-alpha agonist with additional gamma agonist) | sanofi-aventis <i>Bridgewater, NJ</i> | type 2 diabetes | Phase II (800) 633-1610 |
| AVE0897 (balanced PPAR-alpha/ gamma agonist) | sanofi-aventis <i>Bridgewater, NJ</i> | type 2 diabetes | Phase I (800) 633-1610 |
| AVE2268 (SGLT-2 inhibitor) | sanofi-aventis <i>Bridgewater, NJ</i> | type 2 diabetes | Phase II (800) 633-1610 |
| AVE8134 (PPAR-alpha agonist) | sanofi-aventis <i>Bridgewater, NJ</i> | type 2 diabetes | Phase II (800) 633-1610 |
| AVR118 | Advanced Viral Research <i>Yonkers, NY</i> | type 2 diabetes (see also obstetric/gynecologic) | Phase I (914) 376-7383 |
| BHT-3021 | Bayhill Therapeutics <i>Palo Alto, CA</i> | type 1 diabetes | Phase I (650) 320-2800 |
| BI 1356 BS | Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> | type 2 diabetes | Phase II (800) 243-0127 |
| bromocriptine | VeroScience <i>Tiverton, RI</i> Wythe Therapeutics <i>Bristol, TN</i> | type 2 diabetes | Phase III (401) 816-0525 |
| cetilistat | Alizyme <i>Cambridge, UK</i> | type 2 diabetes | Phase II www.alizyme.com |
| CRx-401 | CombinatoRx <i>Cambridge, MA</i> | type 2 diabetes | Phase I (617) 301-7000 |
| CS-917 | Daiichi Sankyo <i>Parsippany, NJ</i> Metabasis Therapeutics <i>San Diego, CA</i> | type 2 diabetes | Phase II (973) 359-2600 (858) 587-2770 |

DIABETES

| Product Name | Company | Indication | Development Status |
|---|--|---|--|
| dapagliflozin (SGLT2 inhibitor) | AstraZeneca <i>Wilmington, DE</i> Bristol-Myers Squibb <i>Princeton, NJ</i> | diabetes | Phase II (800) 236-9933 (212) 546-4000 |
| DiaPep277® | Andromeda <i>Tel-Aviv, Israel</i> | latent autoimmune diabetes in adults | Phase II |
| DIO-902 | DiObex <i>San Francisco, CA</i> | type 2 diabetes | Phase II (415) 551-0400 |
| epidermal growth factor | Novo Nordisk <i>Princeton, NJ</i> Transition Therapeutics <i>Toronto, ON</i> | type 1 diabetes, type 2 diabetes | Phase II (800) 727-6500 (416) 260-7770 |
| exenatide intranasal | Amylin Pharmaceuticals <i>San Diego, CA</i> Nastech Pharmaceutical <i>Bothell, WA</i> | type 2 diabetes | Phase I (858) 552-2200 (425) 908-3600 |
| exenatide LAR (long-acting release) | Alkermes <i>Cambridge, MA</i> Amylin Pharmaceuticals <i>San Diego, CA</i> Eli Lilly <i>Indianapolis, IN</i> | type 2 diabetes | Phase II (617) 494-0171 (858) 552-2200 (800) 545-5979 |
| Galvus® vildagliptin | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | type 2 diabetes | application submitted (888) NOW-NOVA |
| GLP-1 agonist | Bristol-Myers Squibb <i>Princeton, NJ</i> | diabetes | Phase I (212) 546-4000 |
| GLP-1 analogue | Eli Lilly <i>Indianapolis, IN</i> | type 2 diabetes | Phase I (800) 545-5979 |
| INCB 13739 | Incyte <i>Wilmington, DE</i> | type 2 diabetes | Phase II (302) 498-6944 |
| INGAP peptide | Procter & Gamble Pharmaceuticals <i>Cincinnati, OH</i> | type 1 diabetes, type 2 diabetes | Phase I |
| inhalation insulin | Innovata <i>Nottingham, UK</i> MicroDose Technologies <i>Monmouth Junction, NJ</i> | diabetes | Phase I (212) 546-4000 |
| insulin inhalation | Alkermes <i>Cambridge, MA</i> Eli Lilly <i>Indianapolis, IN</i> | diabetes | Phase III (617) 494-0171 (800) 545-5979 |
| insulin inhalation (KI 02212) | Abbott Laboratories <i>Abbott Park, IL</i> | diabetes | Phase II (847) 937-6100 |
| insulin intranasal | Nastech Pharmaceutical <i>Bothell, WA</i> | diabetes | Phase I (425) 908-3600 |
| insulin transdermal | Dermisonics <i>Irvine, CA</i> | type 1 diabetes, type 2 diabetes | Phase I (888) 401-3376 |

DIABETES

| Product Name | Company | Indication | Development Status |
|---------------------------------------|--|-----------------|--|
| INT 131 | InteKrin Therapeutics <i>Los Altos, CA</i> | type 2 diabetes | Phase II (650) 941-5501 |
| Intesulin™ insulin oral | Coremed <i>Lake Bluff, IL</i> | diabetes | Phase I (847) 772-6868 |
| ISIS 113715 | Isis Pharmaceuticals <i>Carlsbad, CA</i> | type 2 diabetes | Phase II (760) 931-9200 |
| K-111 | Kowa Pharmaceuticals <i>Morrisville, NC</i> | type 2 diabetes | Phase II (919) 433-1600 |
| KRP 104 | ActivX Biosciences <i>La Jolla, CA</i> | type 2 diabetes | Phase I (858) 558-5558 |
| liraglutide (NN2211) | Novo Nordisk <i>Princeton, NJ</i> | type 2 diabetes | Phase III (800) 727-6500 |
| MB 07803 | Metabasis Therapeutics <i>San Diego, CA</i> | type 2 diabetes | Phase II (858) 587-2770 |
| MBX-2044 | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> Metabolex <i>Hayward, CA</i> | type 2 diabetes | Phase II (800) 817-5286 (510) 293-8800 |
| metaglidase (MBX-102) | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> Metabolex <i>Hayward, CA</i> | type 2 diabetes | Phase II (800) 817-5286 (510) 293-8800 |
| metformin buccal (chewing gum) | Generex Biotechnology <i>Toronto, ON</i> | type 2 diabetes | in clinical trials (416) 364-2551 |
| mitiglinide | Elixir Pharmaceuticals <i>Cambridge, MA</i> | type 2 diabetes | Phase II (617) 995-7000 |
| MK-0533 | Merck <i>Whitehouse Station, NJ</i> | diabetes | Phase II (800) 672-6372 |
| MK-0893 | Merck <i>Whitehouse Station, NJ</i> | diabetes | Phase I (800) 672-6372 |
| MK-0941 | Merck <i>Whitehouse Station, NJ</i> | diabetes | Phase I (800) 672-6372 |
| MK-1642 | Merck <i>Whitehouse Station, NJ</i> | type 2 diabetes | Phase I (800) 672-6372 |
| MK-3887 | Merck <i>Whitehouse Station, NJ</i> | diabetes | Phase I (800) 672-6372 |
| Nasulin™ insulin intranasal | Bentley Pharmaceuticals <i>Exeter, NH</i> | type 1 diabetes | Phase II (603) 658-6100 |
| Naturlose® tagatose | Spherix <i>Beltsville, MD</i> | type 2 diabetes | Phase III (301) 419-3900 |

DIABETES

| Product Name | Company | Indication | Development Status |
|--|--|-----------------|---|
| naveglitazar (PPAR modulator) | Eli Lilly <i>Indianapolis, IN</i> Ligand Pharmaceuticals <i>San Diego, CA</i> | type 2 diabetes | Phase II (800) 545-5979 (858) 550-7500 |
| NBI-6024 | Neurocrine Biosciences <i>San Diego, CA</i> | type 1 diabetes | Phase II (858) 617-7600 |
| ONO 5129 | Ono Pharma USA <i>Lawrenceville, NJ</i> | type 2 diabetes | Phase II |
| oral insulin | Emisphere Technologies <i>Tarrytown, NY</i> | type 2 diabetes | Phase II (914) 347-2220 |
| PEG-encapsulated islet cell transplantation therapy | Novocell <i>San Diego, CA</i> | type 1 diabetes | Phase I (858) 455-3708 |
| PF-734200 | Pfizer <i>New York, NY</i> | type 2 diabetes | Phase II (860) 732-5156 |
| PF-915275 | Pfizer <i>New York, NY</i> | type 2 diabetes | Phase I (860) 732-5156 |
| PHX 1149 | Phenomix <i>San Diego, CA</i> | type 2 diabetes | Phase II (858) 731-5200 |
| pioglitazone/ metformin extended-release | Takeda Pharmaceuticals North America <i>Deerfield, IL</i> | type 2 diabetes | application submitted (224) 554-6500 |
| PPM 201 | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | type 2 diabetes | Phase I (800) 934-5556 |
| PPM 202 | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | type 2 diabetes | Phase I (800) 934-5556 |
| PPM 204 | Plexxikon <i>Berkeley, CA</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i> | type 2 diabetes | Phase II (510) 647-4000 (800) 934-5556 |
| Promaxx™ recombinant human insulin inhalation powder | Baxter Healthcare <i>Deerfield, IL</i> | diabetes | Phase I (800) 4-BAXTER |
| pyrazinoyl- guanidine | SuperGen <i>Dublin, CA</i> | type 2 diabetes | Phase II (925) 560-0100 |
| rivoglitazone | Daiichi Sankyo <i>Parsippany, NJ</i> | type 2 diabetes | Phase II (973) 359-2600 |
| RO 0730699 | Roche <i>Nutley, NJ</i> | type 2 diabetes | Phase II (973) 235-5000 |
| RO 4389620 | Roche <i>Nutley, NJ</i> | type 2 diabetes | Phase II (973) 235-5000 |
| saxagliptin (DPP4 inhibitor) | AstraZeneca <i>Wilmington, DE</i> Bristol-Myers Squibb <i>Princeton, NJ</i> | type 2 diabetes | Phase III (800) 236-9933 (212) 546-4000 |

DIABETES

| Product Name | Company | Indication | Development Status |
|--|---|--|---|
| SRT-501 | Sirtris Pharmaceuticals <i>Cambridge, MA</i> | type 2 diabetes | Phase I (617) 252-6920 |
| TA 6666 | Tanabe Seiyaku <i>Osaka, Japan</i> | type 2 diabetes | Phase II |
| Technosphere® Insulin insulin inhalation | MannKind <i>Valencia, CA</i> | type 1 diabetes, type 2 diabetes | Phase III (661) 725-5300 |
| teplizumab | MacroGenics <i>Rockville, MD</i> | type 1 diabetes (see also autoimmune) | Phase II (301) 251-5172 |
| TPP 355 | TransTech Pharma <i>High Point, NC</i> | diabetes | Phase I (336) 841-0300 |
| TRX4 (anti-CD3 MAb) | Tolerrx <i>Cambridge, MA</i> | type 1 diabetes (see also autoimmune) | Phase I (617) 354-8100 |
| TS-021 | Taisho Pharmaceutical R&D <i>Morristown, NJ</i> | type 2 diabetes | Phase I |
| WelChol® colesevelam | Daiichi Sankyo <i>Parsippany, NJ</i> | type 2 diabetes | application submitted (973) 359-2600 |

EYE DISORDERS

| Product Name | Company | Indication | Development Status |
|--|---|------------|---|
| ALTY-0501 | Alacrity Biosciences <i>Laguna Hills, CA</i> | dry eyes | Phase II (949) 951-1348 |
| C-3859 | Merck <i>Whitehouse Station, NJ</i> | glaucoma | Phase I (800) 672-6372 |
| C-9993 | Merck <i>Whitehouse Station, NJ</i> | glaucoma | Phase I (800) 672-6372 |
| Combigan™ brimonidine/ timolol combination | Allergan <i>Irvine, CA</i> | glaucoma | application submitted (714) 246-4500 |
| DuoTrav™ travoprost/timolol | Alcon Research <i>Fort Worth, TX</i> | glaucoma | application submitted (800) 862-5266 |
| duramycin | Lantibio <i>Chapel Hill, NC</i> | dry eyes | Phase II (919) 960-0217 |
| ecabet | ISTA Pharmaceuticals <i>Irvine, CA</i> | dry eyes | Phase II (949) 788-6000 |
| Evoxac® cevimeline | Daiichi Sankyo <i>Parsippany, NJ</i> | dry eyes | in clinical trials (973) 359-2600 |
| Ganfort® bimatoprost/ timolol combination | Allergan <i>Irvine, CA</i> | glaucoma | application submitted (714) 246-4500 |

EYE DISORDERS

| Product Name | Company | Indication | Development Status |
|---|---|------------|---|
| INS115644 | Inspire Pharmaceuticals <i>Durham, NC</i> | glaucoma | Phase I (919) 941-9777 |
| memantine | Allergan <i>Irvine, CA</i> | glaucoma | Phase III (714) 246-4500 |
| NP50301 | Nascent Pharmaceuticals <i>Rsch. Triangle Park, NC</i> | dry eyes | Phase II (919) 806-4569 |
| OT-551 | Othera Pharmaceuticals <i>Exton, PA</i> | cataracts | Phase II (877) 551-8240 |
| | | dry eyes | Phase I (877) 551-8240 |
| PF-03187207 | Pfizer <i>New York, NY</i> | glaucoma | Phase II (860) 732-5156 |
| Prolacria TM diquafosol | Inspire Pharmaceuticals <i>Durham, NC</i> | dry eyes | application submitted (919) 941-9777 |
| rebamipide eye drops | Novartis Pharmaceuticals <i>East Hanover, NJ</i> Otsuka America Pharmaceutical <i>Rockville, MD</i> | dry eyes | Phase III (888) NOW-NOVA (800) 562-3974 |
| Retaane [®] anecortave acetate | Alcon Research <i>Fort Worth, TX</i> | glaucoma | Phase II (800) 862-5266 |
| tafluprost (DE-085) | Santen <i>Napa, CA</i> | glaucoma | Phase III (707) 254-1750 |
| Vexol [®] rimexolone | Alcon Research <i>Fort Worth, TX</i> | dry eyes | Phase II (800) 862-5266 |

GASTROINTESTINAL DISORDERS

| Product Name | Company | Indication | Development Status |
|--|--|--|---|
| 561679 (CRF1 antagonist) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> Neurocrine Biosciences <i>San Diego, CA</i> | irritable bowel syndrome (see also psychiatric) | Phase I (888) 825-5249 (858) 617-7600 |
| 876008 (CRF1 antagonist) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> Neurocrine Biosciences <i>San Diego, CA</i> | irritable bowel syndrome (see also psychiatric) | Phase II (888) 825-5249 (858) 617-7600 |
| Amitiza TM lubiprostone | Sucampo Pharmaceuticals <i>Bethesda, MD</i> Takeda Pharmaceuticals North America <i>Deerfield, IL</i> | irritable bowel syndrome | application submitted (301) 961-3400 (224) 554-6500 |

GASTROINTESTINAL DISORDERS

| Product Name | Company | Indication | Development Status |
|------------------------------|---|--|---|
| asimadoline | Tioga Pharmaceuticals <i>San Diego, CA</i> | irritable bowel syndrome | Phase II (858) 677-6077 |
| AV-608 | Avera Pharmaceuticals <i>San Diego, CA</i> | irritable bowel syndrome | Phase I (858) 847-0650 |
| crofelemer | Napo Pharmaceuticals <i>South San Francisco, CA</i> Trine Pharmaceuticals <i>Waltham, MA</i> | irritable bowel syndrome | Phase II (650) 616-1900 (781) 647-5554 |
| DDP-225 | Dynogen Pharmaceuticals <i>Waltham, MA</i> | irritable bowel syndrome | Phase II (781) 839-5100 |
| dextofisopam | Vela Pharmaceuticals <i>Ewing, NJ</i> | irritable bowel syndrome | Phase II (609) 771-8660 |
| linaclotide | Microbia <i>Cambridge, MA</i> | irritable bowel syndrome | Phase II (617) 621-7722 |
| LX1031 | Lexicon Pharmaceuticals <i>The Woodlands, TX</i> | irritable bowel syndrome | Phase I (281) 863-3000 |
| mitemcinal | Chugai Pharma USA <i>Bedminster, NJ</i> | irritable bowel syndrome | Phase II (908) 947-2700 |
| Paxil® paroxetine | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | irritable bowel syndrome (see also autoimmune) | Phase II (888) 825-5249 |
| PD-217014 | Pfizer <i>New York, NY</i> | irritable bowel syndrome (see also kidney/urologic) | Phase II (860) 732-5156 |
| renzapride | Alizyme <i>Cambridge, UK</i> | irritable bowel syndrome | Phase III www.alizyme.com |
| RWJ-68023 | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> | irritable bowel syndrome | Phase I (800) 817-5286 |
| Xifaxan™ rifaximin | Salix Pharmaceuticals <i>Morrisville, NC</i> | irritable bowel syndrome | Phase II (919) 862-1000 |

KIDNEY/UROLOGIC DISORDERS

| Product Name | Company | Indication | Development Status |
|---|--|--------------------------|----------------------------|
| 366074 (potassium channel opener) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | overactive bladder | Phase I (888) 825-5249 |
| AA 4010 | Auxilium Pharmaceuticals <i>Malvern, PA</i> | overactive bladder | Phase I (484) 321-5900 |
| ABT-492 | Rib-X Pharmaceuticals <i>New Haven, CT</i> | urinary tract infections | Phase II (203) 624-5606 |
| ABT-598 | Abbott Laboratories <i>Abbott Park, IL</i> | overactive bladder | Phase I (847) 937-6100 |

KIDNEY/UROLOGIC DISORDERS

| Product Name | Company | Indication | Development Status |
|--|--|--|---|
| botulinum toxin A | Allergan <i>Irvine, CA</i> | overactive bladder | Phase II (714) 246-4500 |
| C-0172 | Merck <i>Whitehouse Station, NJ</i> | urinary incontinence | Phase I (800) 672-6372 |
| C-4699 | Merck <i>Whitehouse Station, NJ</i> | urinary incontinence | Phase I (800) 672-6372 |
| casopitant (NK1 antagonist) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | overactive bladder (see also psychiatric) | Phase II (888) 825-5249 |
| CellCept® mycophenolate mofetil | Aspreva Pharmaceuticals <i>Victoria, BC</i> Roche <i>Nutley, NJ</i> | lupus nephritis (see also arthritis/musculoskeletal) | Phase III (250) 744-2488 (973) 235-5000 |
| CTV-05 | Osel <i>Santa Clara, CA</i> | urinary tract infections (see also obstetric/gynecologic) | Phase II (408) 986-0012 |
| Cubicin® daptomycin injectable | Cubist Pharmaceuticals <i>Lexington, MA</i> | urinary tract infections | Phase III (781) 860-8660 |
| Cystin CR® oxybutynin | Penwest Pharmaceuticals <i>Danbury, CT</i> | urinary incontinence | in clinical trials (203) 796-3700 |
| Cystistat® hyaluron intravesical | Bioniche Teorants <i>County Galway, Ireland</i> | interstitial cystitis | Phase III |
| DDP-200 | Dynogen Pharmaceuticals <i>Waltham, MA</i> | overactive bladder | Phase II (781) 839-5100 |
| doripenem | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> Shionogi USA <i>Florham Park, NJ</i> | urinary tract infections | application submitted (800) 817-5286 (973) 966-6900 |
| Enhance UI™ oxybutynin transvaginal ring (TVR) | Barr Laboratories <i>Pomona, NY</i> | urinary incontinence | Phase II (800) 222-0190 |
| Factive® gemifloxacin | Oscient Pharmaceuticals <i>Waltham, MA</i> | urinary tract infections | application submitted (781) 398-2300 |
| fesoterodine | Schwarz Pharma <i>Mequon, WI</i> | overactive bladder | application submitted (262) 238-5400 |
| | | urinary incontinence | Phase III (262) 238-5400 |
| FP1097 | FemmePharma Global Healthcare <i>Wayne, PA</i> | urinary incontinence | Phase II (610) 995-0801 |

KIDNEY/UROLOGIC DISORDERS

| Product Name | Company | Indication | Development Status |
|--|---|--|---|
| garenoxacin | Schering-Plough <i>Kenilworth, NJ</i> | urinary tract infections | Phase III (908) 298-4000 |
| KW-7158 | Kyowa Pharmaceutical <i>Princeton, NJ</i> | overactive bladder | Phase II (609) 919-1100 |
| Levaquin® levofloxacin | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> | urinary tract infections (see also lung/respiratory) | application submitted (800) 817-5286 |
| MK-0594 | Merck <i>Whitehouse Station, NJ</i> | overactive bladder | Phase II (800) 672-6372 |
| MK-0634 | Merck KGaA <i>Darmstadt, Germany</i> | overactive bladder, urinary incontinence | Phase II |
| MN-001 | MediciNova <i>San Diego, CA</i> | interstitial cystitis | Phase II (858) 373-1500 |
| MN-246 | MediciNova <i>San Diego, CA</i> | urinary incontinence | Phase I (858) 373-1500 |
| PD-217014 | Pfizer <i>New York, NY</i> | overactive bladder (see also gastrointestinal) | Phase II (860) 732-5156 |
| prulifloxacin | Optimer Pharmaceuticals <i>San Diego, CA</i> | urinary tract infections | Phase II (858) 909-0736 |
| PSD-597 | Plethora Solutions <i>London, England</i> | interstitial cystitis | Phase II |
| Riquent® abetimus | La Jolla Pharmaceutical <i>San Diego, CA</i> | lupus nephritis | application submitted (858) 452-6600 |
| Rituxan® rituximab | Biogen Idec <i>Cambridge, MA</i> Genentech <i>South San Francisco, CA</i> | lupus nephritis (see also arthritis/musculoskeletal, autoimmune) | Phase III (617) 679-2000 (650) 225-1000 |
| Sanctura® XR trospium chloride (extended-release) | Indevis Pharmaceuticals <i>Lexington, MA</i> | overactive bladder | application submitted (781) 861-8444 |
| SMP-986 | Dainippon Sumitomo Pharma <i>Osaka, Japan</i> | overactive bladder | Phase II |
| SSR 240600 (NK1 antagonist) | sanofi-aventis <i>Bridgewater, NJ</i> | overactive bladder, urge urinary incontinence | Phase II (800) 633-1610 |
| suplatast tosilate | Astellas Pharma US <i>Deerfield, IL</i> | interstitial cystitis | Phase II (800) 695-4321 |
| UTI vaccine | Xanodyne Pharmaceuticals <i>Florence, KY</i> | urinary tract infections | Phase II (859) 371-6383 |
| Vestra® reboxetine | Pfizer <i>New York, NY</i> | urinary incontinence (see also psychiatric) | Phase II (860) 732-5156 |

LUNG/RESPIRATORY DISORDERS

| Product Name | Company | Indication | Development Status |
|---|--|--|--|
| 159797 (long-acting beta2 agonist) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | asthma (in combination with a glucocorticoid agonist) | Phase II (888) 825-5249 |
| 597901 (long-acting beta2 agonist) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | asthma (in combination with a glucocorticoid agonist) | Phase II (888) 825-5249 |
| 642444 (long-acting beta2 agonist) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | asthma (in combination with a glucocorticoid agonist) | Phase II (888) 825-5249 |
| 799943 (glucocorticoid agonist) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | asthma (in combination with a long-acting beta2 agonist) | Phase II (888) 825-5249 |
| ABN 912 | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | asthma | Phase I (888) NOW-NOVA |
| AER-001 | Aerovance <i>Berkeley, CA</i> | acute asthma | Phase II (510) 549-5500 |
| Allegra [®] fexofenadine (disintegrating tablets) | sanofi-aventis <i>Bridgewater, NJ</i> | asthma | application submitted (800) 633-1610 |
| Alvesco [®] ciclesonide (MDI) | Altana Pharma US (Nycomed) <i>Florham Park, NJ</i> | asthma | application submitted (973) 514-4240 |
| Alvesco [®] Combo ciclesonide/ formoterol | Altana Pharma US (Nycomed) <i>Florham Park, NJ</i> sanofi-aventis <i>Bridgewater, NJ</i> | asthma | Phase II (973) 514-4240 (800) 633-1610 |
| AMG 317 | Amgen <i>Thousand Oaks, CA</i> | asthma | Phase I (805) 447-1000 |
| ASM8 | Topigen Pharmaceuticals <i>Montreal, QC</i> | asthma | Phase II (514) 868-0077 |
| Augmentin XR [®] amoxicillin/ clavulanic acid controlled release | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | acute exacerbations of chronic bronchitis | Phase III (888) 825-5249 |
| AVE8923 | sanofi-aventis <i>Bridgewater, NJ</i> | asthma | Phase I (800) 633-1610 |
| AVP-13358 | Avanir Pharmaceuticals <i>San Diego, CA</i> | allergic asthma | Phase I (858) 622-5200 |
| Azmacort HFA [®] triamcinolone acetone hydrofluoroalkane inhalation | Abbott Laboratories <i>Abbott Park, IL</i> | asthma | Phase III (847) 937-6100 |

LUNG/RESPIRATORY DISORDERS

| Product Name | Company | Indication | Development Status |
|---|--|--|--|
| beclometasone hydrofluoroalkane inhalation | IVAX <i>Miami, FL</i> | asthma | Phase III (305) 575-6000 |
| bedoradrine (MN-221) | MediciNova <i>San Diego, CA</i> | status asthmaticus (see also obstetric/gynecologic) | Phase II (858) 373-1500 |
| BIW-8405 | MedImmune <i>Gaithersburg, MD</i> | asthma | Phase I (301) 398-0000 |
| budesonide inhalation | MAP Pharmaceuticals <i>Mountain View, CA</i> | asthma | Phase II (650) 386-3100 |
| CHF-5188 | Chiesi Pharmaceuticals <i>Rockville, MD</i> | asthma | Phase II (301) 424-2661 |
| CS-003 | Daiichi Sankyo <i>Parsippany, NJ</i> | asthma | Phase II (973) 359-2600 |
| CS-615 | Daiichi Sankyo <i>Parsippany, NJ</i> | asthma | Phase II (973) 359-2600 |
| CTI 02 (zileuton) | Critical Therapeutics <i>Lexington, MA</i> | asthma | Phase III (781) 402-5700 |
| CVT 6883 | CV Therapeutics <i>Palo Alto, CA</i> | asthma | Phase I (650) 384-8500 |
| Daxas [®] roflumilast | Altana Pharma US (Nycomed) <i>Florham Park, NJ</i> | asthma | Phase III (973) 514-4240 |
| EPI-12323 | EpiGenesis Pharmaceuticals <i>Cranbury, NJ</i> | asthma | Phase II (609) 409-6080 |
| epinastine | Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> | asthma | Phase I (203) 798-9988 |
| etiprednol | IVAX <i>Miami, FL</i> | asthma | Phase II (305) 575-6000 |
| faropenem medoxomil | Asubio Pharmaceuticals <i>Rochelle Park, NJ</i> | acute exacerbations of chronic bronchitis | Phase III (201) 368-5020 |
| Flutiform [™] formoterol/fluticasone propionate | SkyePharma <i>San Diego, CA</i> | asthma | Phase III (858) 625-2424 |
| formoterol hydrofluoroalkane inhalation | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | asthma | Phase II (888) NOW-NOVA |
| golimumab | Centocor <i>Horsham, PA</i> Schering-Plough <i>Kenilworth, NJ</i> | asthma (see also arthritis/musculoskeletal) | Phase II (610) 651-6000 (908) 298-4000 |
| HAE-1 | Genentech <i>South San Francisco, CA</i> | moderate to severe allergic asthma | Phase II (650) 225-1000 |

LUNG/RESPIRATORY DISORDERS

| Product Name | Company | Indication | Development Status |
|---|---|--|---|
| IL-4/13 trap | Regeneron Pharmaceuticals <i>Tarrytown, NY</i> | asthma | Phase I (914) 345-7400 |
| IMA-638 | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | asthma | Phase II (800) 934-5556 |
| INV102 | Inverseon <i>San Francisco, CA</i> | asthma | Phase II (415) 440-7400 |
| isatoribine | Anadys <i>San Diego, CA</i> | asthma | Phase I (858) 373-1500 |
| Kineret [®] anakinra | Amgen <i>Thousand Oaks, CA</i> | asthma (see also arthritis/musculoskeletal) | Phase II (805) 447-1000 |
| Levaquin [®] levofloxacin | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> | acute exacerbations of chronic bronchitis (see also kidney/urologic) | application submitted (800) 817-5286 |
| lumiliximab | Biogen Idec <i>Cambridge, MA</i> | allergic asthma | Phase II (617) 679-2000 |
| MEDI-528 | MedImmune <i>Gaithersburg, MD</i> | asthma | Phase I (301) 398-0000 |
| mepolizumab (anti-IL-5 MAb) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | severe asthma | Phase II (888) 825-5249 |
| mometasone/ formoterol combination | Schering-Plough <i>Kenilworth, NJ</i> | asthma | Phase III (908) 298-4000 |
| ogemilast | Forest Laboratories <i>New York, NY</i> | asthma | Phase II (800) 947-5227 |
| olopatadine | Alcon Research <i>Fort Worth, TX</i> | asthma | Phase II (800) 862-5266 |
| PB-008 | Inflabloc Pharmaceuticals <i>Salt Lake City, UT</i> | asthma | Phase II (801) 464-6100 |
| phosphodiesterase IV inhibitor | Merck <i>Whitehouse Station, NJ</i> | asthma | Phase I (800) 672-6372 |
| PW-3101 | Penwest Pharmaceuticals <i>Danbury, CT</i> | asthma | application submitted (203) 796-3700 |
| Qvar [®] Easi-Breathe [®] beclometasone breath-activated inhalation | IVAX <i>Miami, FL</i> | asthma | Phase III (305) 575-6000 |
| Remicade [®] infliximab | Centocor <i>Horsham, PA</i> | asthma (see also arthritis/musculoskeletal, autoimmune) | Phase II (610) 651-6000 |
| RWJ-58643 | Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> | asthma | Phase I (800) 817-5286 |

LUNG/RESPIRATORY DISORDERS

| Product Name | Company | Indication | Development Status |
|--|--|--|--|
| salbutamol dry-powder inhalation | Innovata <i>Nottingham, UK</i> | asthma | Phase II |
| Serevent [®] salmeterol MDI dose counter | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | asthma | Phase III (888) 825-5249 |
| Singulair [®] montelukast | Merck <i>Whitehouse Station, NJ</i> | acute asthma | Phase III (800) 672-6372 |
| | | ----- bronchitis | in clinical trials (800) 672-6372 |
| SMP-028 | Dainippon Sumitomo Pharma America <i>Fort Lee, NJ</i> | asthma | Phase I |
| sodium cromoglicate oral | Emisphere Technologies <i>Tarrytown, NY</i> | asthma | Phase I (914) 347-2220 |
| Surfaxin [®] sinapultide | Discovery Laboratories <i>Warrington, PA</i> | asthma | Phase I (215) 488-9300 |
| tacrolimus inhalation | Astellas Pharma US <i>Deerfield, IL</i> | asthma (see also autoimmune) | Phase II (800) 695-4321 |
| TBC-4746 | Encysive Pharmaceuticals <i>Houston, TX</i> Schering-Plough <i>Kenilworth, NJ</i> | asthma (see also autoimmune) | Phase I (713) 796-8822 (908) 298-4000 |
| TNX-650 | Tanox <i>Houston, TX</i> | asthma | Phase I (713) 578-4000 |
| tofimilast | Pfizer <i>New York, NY</i> | asthma | Phase II (860) 732-5156 |
| Zenapax [®] daclizumab | Biogen Idec <i>Cambridge, MA</i> PDL BioPharma <i>Fremont, CA</i> | asthma (see also neurologic) | Phase II (617) 679-2000 (510) 574-1632 |
| Zmax [™] azithromycin controlled-release microspheres | Pfizer <i>New York, NY</i> | acute exacerbations of chronic bronchitis | application submitted (860) 732-5156 |

NEUROLOGIC DISORDERS

| Product Name | Company | Indication | Development Status |
|---------------------------|--|--|----------------------------|
| AAB-001 (bapineuzumab) | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | Alzheimer's disease (passive immunotherapy) | Phase II (800) 934-5556 |

NEUROLOGIC DISORDERS

| Product Name | Company | Indication | Development Status |
|--|--|---|---|
| AAV-NGF (CERE-110) (gene therapy) | Ceregene <i>San Diego, CA</i> | Alzheimer's disease | Phase I (858) 458-8800 |
| AC-1202 | Accera <i>Broomfield, CO</i> | Alzheimer's disease, memory disorders | Phase II (303) 439-0004 |
| ACC-001 | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | Alzheimer's disease | Phase I (800) 934-5556 |
| AL-108 | Allon Therapeutics <i>Vancouver, BC</i> | Alzheimer's disease | Phase I (604) 736-0634 |
| Alzhemed™ tramiprosate | Neurochem <i>Laval, QC</i> | Alzheimer's disease | Phase III (450) 680-4500 |
| Aricept® donepezil HCl | Eisai <i>Ridgefield Park, NJ</i> Pfizer <i>New York, NY</i> | mild cognitive impairment | Phase III (888) 274-2378 (860) 732-5156 |
| | | migraine | Phase II (888) 274-2378 (860) 732-5156 |
| AST-726 | Ariston Pharmaceuticals <i>Framingham, MA</i> | migraine | Phase I (508) 665-4260 |
| AV-965 | Avera Pharmaceuticals <i>San Diego, CA</i> | Alzheimer's disease, cognition disorders | Phase I (858) 847-0650 |
| Avandia® rosiglitazone | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | Alzheimer's disease (see also diabetes) | Phase II (888) 825-5249 |
| AVE1625 (selective CB1 antagonist) | sanofi-aventis <i>Bridgewater, NJ</i> | Alzheimer's disease | Phase II (800) 633-1610 |
| AVE8112 (PDE IV inhibitor) | sanofi-aventis <i>Bridgewater, NJ</i> | Alzheimer's disease | Phase I (800) 633-1610 |
| Azilect® rasagiline XR mesylate | Teva Pharmaceuticals USA <i>North Wales, PA</i> | Alzheimer's disease | Phase II (215) 591-3000 |
| BIBN-4096 | Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> | migraine | Phase II (203) 798-9988 |
| butorphanol intranasal | Intranasal Therapeutics <i>Montvale, NJ</i> | migraine | Phase III (859) 252-5080 |
| C-9138 | Merck <i>Whitehouse Station, NJ</i> | Alzheimer's disease | Phase I (800) 672-6372 |
| civamide | Winston Laboratories <i>Vernon Hills, IL</i> | migraine | Phase II (847) 362-8200 |
| Corlux™ mifepristone | Corcept Therapeutics <i>Menlo Park, CA</i> | Alzheimer's disease (see also cancer, psychiatric) | Phase II (650) 327-3270 |

NEUROLOGIC DISORDERS

| Product Name | Company | Indication | Development Status |
|---|--|-------------------------------------|---|
| CX-717 | Cortex Pharmaceuticals <i>Irvine, CA</i> | Alzheimer's disease | Phase II (949) 727-3157 |
| diclofenac | ProEthic Pharmaceuticals <i>Montgomery, AL</i> | migraine | application submitted (334) 288-1288 |
| dihydroergotamine inhaled | MAP Pharmaceuticals <i>Mountain View, CA</i> | migraine | Phase II (650) 386-3100 |
| docosahexaenoic acid (DHA) | Martek Biosciences <i>Columbia, MD</i> | Alzheimer's disease | Phase III (410) 740-0081 |
| E2007 | Eisai <i>Ridgefield Park, NJ</i> | migraine (see also autoimmune) | Phase II (888) 274-2378 |
| EGb-761 | Ipsen <i>Milford, MA</i> | Alzheimer's disease | Phase III (508) 478-8900 |
| Emsam [®] selegiline transdermal | Somerset Pharmaceuticals <i>Tampa, FL</i> | Alzheimer's disease | Phase III |
| | | cognition disorders | Phase II |
| estrogen therapeutic | Migenix <i>Vancouver, BC</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i> | Alzheimer's disease | Phase III (604) 221-9666 (610) 902-1200 |
| FHPC-01 | Sciele Pharma <i>Atlanta, GA</i> | migraine | Phase I (800) 461-3696 |
| Flurizan [™] tarenflurbil | Myriad Genetics <i>Salt Lake City, UT</i> | Alzheimer's disease | Phase III (801) 584-3600 |
| Frova [®] frovatriptan | Endo Pharmaceuticals <i>Chadds Ford, PA</i> | prevention of menstrual migraine | application submitted (610) 558-9800 |
| GABA A receptor agonist | Merck <i>Whitehouse Station, NJ</i> | Alzheimer's disease | Phase I (800) 672-6372 |
| GTS-21 | CoMentis <i>South San Francisco, CA</i> | Alzheimer's disease | Phase II (650) 869-7600 |
| HT-0712 (IPL455,903) | Helicon Therapeutics <i>Farmingdale, NY</i> Inflazyme Pharmaceuticals <i>Richmond, BC</i> | cognition disorders | Phase I (631) 370-8834 (800) 315-3660 |
| huperzine A | Neuro-Hitech <i>New York, NY</i> | Alzheimer's disease | Phase II (212) 594-1215 |
| immune globulin | Baxter Healthcare <i>Deerfield, IL</i> | Alzheimer's disease | Phase II (800) 4-BAXTER |
| Intraject [®] sumatriptan (needle-free) | Zogenix <i>San Diego, CA</i> | migraine | Phase III (858) 259-1165 |
| ispronlicline (TC-1734) | AstraZeneca <i>Wilmington, DE</i> Targacept <i>Winston-Salem, NC</i> | cognition disorders | Phase II (800) 236-9933 (336) 480-2100 |

NEUROLOGIC DISORDERS

| Product Name | Company | Indication | Development Status |
|---------------------------------|--|--|--|
| lacosamide | Schwarz Pharma <i>Mequon, WI</i> | migraine (see also autoimmune) | Phase III (262) 238-5400 |
| lecozotan (SRA-333) | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | Alzheimer's disease | Phase II (610) 902-1200 |
| leuprorelin | Durect <i>Cupertino, CA</i> Voyager Pharmaceutical <i>Raleigh, NC</i> | Alzheimer's disease | Phase III (919) 846-4880 |
| levacecarnine | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | Alzheimer's disease | Phase III (888) 825-5249 |
| Lipitor® atorvastatin | Pfizer <i>New York, NY</i> | Alzheimer's disease | Phase II (860) 732-5156 |
| lornoxicam | POZEN <i>Chapel Hill, NC</i> | migraine | Phase II (919) 913-1030 |
| LY-2062430 | Eli Lilly <i>Indianapolis, IN</i> | Alzheimer's disease | Phase II (800) 545-5979 |
| LY-450139 | Eli Lilly <i>Indianapolis, IN</i> | Alzheimer's disease | Phase II (800) 545-5979 |
| LY-451395 | Eli Lilly <i>Indianapolis, IN</i> | Alzheimer's disease | Phase II (800) 545-5979 |
| MEM-1003 | Memory Pharmaceuticals <i>Montvale, NJ</i> | Alzheimer's disease | Phase II (201) 802-7100 |
| | | ----- mild cognitive impairment | Phase I (201) 802-7100 |
| MEM-1414 | Memory Pharmaceuticals <i>Montvale, NJ</i> | Alzheimer's disease, mild cognitive impairment | Phase I (201) 802-7100 |
| MEM-3454 | Memory Pharmaceuticals <i>Montvale, NJ</i> Roche <i>Nutley, NJ</i> | Alzheimer's disease | Phase II (201) 802-7100 (973) 235-5000 |
| | | ----- cognition disorders | Phase I (201) 802-7100 (973) 235-5000 |
| MK-0249 | Merck <i>Whitehouse Station, NJ</i> | Alzheimer's disease | Phase II (800) 672-6372 |
| MK-0752 | Merck <i>Whitehouse Station, NJ</i> | Alzheimer's disease (see also cancer) | Phase I (800) 672-6372 |
| MK-0952 | Merck <i>Whitehouse Station, NJ</i> | Alzheimer's disease | Phase I (800) 672-6372 |
| neramexane | Forest Laboratories <i>New York, NY</i> | Alzheimer's disease | Phase III (800) 947-5227 |
| Neurontin® gabapentin | Pfizer <i>New York, NY</i> | migraine (see also obstetric/gynecologic, psychiatric) | Phase II (860) 732-5156 |

NEUROLOGIC DISORDERS

| Product Name | Company | Indication | Development Status |
|--|--|---|--|
| NGX-267 | TorreyPines Therapeutics <i>La Jolla, CA</i> | Alzheimer's disease | Phase I (858) 623-5665 |
| NGX-426 | TorreyPines Therapeutics <i>La Jolla, CA</i> | migraine | Phase I (858) 623-5665 |
| NP-101 | NuPathe <i>Conshohocken, PA</i> | migraine | Phase I (484) 567-0130 |
| ONO-2506 | Ono Pharma USA <i>Lawrenceville, NJ</i> | Alzheimer's disease | Phase II |
| paliroden (SR 57667) | sanofi-aventis <i>Bridgewater, NJ</i> | Alzheimer's disease | Phase II (800) 633-1610 |
| PAZ-417 | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | Alzheimer's disease | Phase I (800) 934-5556 |
| PF-3084014 | Pfizer <i>New York, NY</i> | Alzheimer's disease | Phase I (860) 732-5156 |
| PNU-142633F | Pfizer <i>New York, NY</i> | migraine | Phase II (860) 732-5156 |
| prochlorperazine inhalation (AZ001) | Alexza Pharmaceuticals <i>Palo Alto, CA</i> | migraine | Phase II (650) 687-3900 |
| PRX-03140 | EPIX Pharmaceuticals <i>Lexington, MA</i> GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | Alzheimer's disease | Phase II (781) 761-7600 (888) 825-5249 |
| PRX-07034 | EPIX Pharmaceuticals <i>Lexington, MA</i> | Alzheimer's disease, cognition disorders | Phase I (781) 761-7600 |
| Relpax [®] eletriptan | Pfizer <i>New York, NY</i> | menstrual migraine | in clinical trials (860) 732-5156 |
| rizatriptan | Merck <i>Whitehouse Station, NJ</i> | menstrual migraine | Phase III (800) 672-6372 |
| rosiglitazone XR | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | Alzheimer's disease | Phase III (888) 825-5249 |
| Rozerem [™] ramelteon | Takeda Pharmaceuticals North America <i>Deerfield, IL</i> | Alzheimer's disease | Phase II (224) 554-6500 |
| SAM-315 | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | Alzheimer's disease | Phase I (800) 934-5556 |
| SAM-531 | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | Alzheimer's disease | Phase I (800) 934-5556 |
| Sermion [®] nicergoline | Pfizer <i>New York, NY</i> | Alzheimer's disease | Phase III (860) 732-5156 |
| SGS-742 | Saegis Pharmaceuticals <i>Half Moon Bay, CA</i> | Alzheimer's disease, mild cognitive impairment | Phase II (650) 560-0210 |

NEUROLOGIC DISORDERS

| Product Name | Company | Indication | Development Status |
|--|---|---------------------|--|
| SIB-1553A | Merck <i>Whitehouse Station, NJ</i> | Alzheimer's disease | Phase II (800) 672-6372 |
| SSR 180711 (alpha-7 nicotinic agonist) | sanofi-aventis <i>Bridgewater, NJ</i> | Alzheimer's disease | Phase I (800) 633-1610 |
| sumatriptan oral spray | NovaDel Pharma <i>Flemington, NJ</i> | migraine | Phase I (908) 782-3431 |
| T-817MA | Toyama Chemical <i>Tokyo, Japan</i> | Alzheimer's disease | Phase I |
| tesofensine (NS-2330) | NeuroSearch <i>Ballerup, Denmark</i> | Alzheimer's disease | Phase II |
| tezampanel | Eli Lilly <i>Indianapolis, IN</i> Torrey Pines Therapeutics <i>La Jolla, CA</i> | migraine | Phase II (800) 545-5979 (858) 623-5665 |
| Trexima™ naproxen sodium/ sumatriptan (fixed-dose combination) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> POZEN <i>Chapel Hill, NC</i> | migraine | application submitted (888) 825-5249 |
| TTP-488 | Pfizer <i>New York, NY</i> TransTech Pharma <i>High Point, NC</i> | Alzheimer's disease | Phase II (860) 732-5156 (336) 841-0300 |
| xaliproden (SR 57746) | sanofi-aventis <i>Bridgewater, NJ</i> | Alzheimer's disease | Phase III (800) 633-1610 |

OBSTETRIC/GYNECOLOGIC CONDITIONS

| Product Name | Company | Indication | Development Status |
|---|--|---|---|
| Actyve™ fertility transdermal patch | Ferring Pharmaceuticals <i>Suffern, NY</i> Vyteris <i>Fair Lawn, NY</i> | female infertility | Phase I (845) 770-2600 (201) 703-2299 |
| Alferon N LDO® interferon-alfa-n3 | Hemispherx Biopharma <i>Philadelphia, PA</i> | human papillomavirus (HPV) infections | in clinical trials (215) 988-0080 |
| Alista™ alprostadil topical | VIVUS <i>Mountain View, CA</i> | female sexual arousal disorder | Phase II (650) 934-5200 |
| Androsorb® testosterone topical | Esprit Pharma <i>East Brunswick, NJ</i> | female sexual dysfunction | Phase II (732) 828-9950 |
| Aprela™ conjugated estrogens/ bazedoxifene | Ligand Pharmaceuticals <i>San Diego, CA</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i> | vaginal atrophy, vasomotor symptoms (see also arthritis/musculoskeletal) | Phase III (858) 550-7500 (800) 934-5556 |

OBSTETRIC/GYNECOLOGIC CONDITIONS

| Product Name | Company | Indication | Development Status |
|---|--|--|---|
| Arcoxia™ etoricoxib | Merck <i>Whitehouse Station, NJ</i> | dysmenorrhea (see also arthritis/musculoskeletal) | Phase III (800) 672-6372 |
| Arimidex® anastrozole | EMD Serono <i>Rockland, MA</i> | endometriosis, infertility (ovulation induction & improvement of follicular development) | Phase II (800) 283-8088 |
| AVR118 | Advanced Viral Research <i>Yonkers, NY</i> | human papillomavirus infections (see also diabetes) | Phase II (914) 376-7383 |
| barusiban | Ferring Pharmaceuticals <i>Parsippany, NJ</i> | preterm labor | Phase II (888) FERRING |
| bedoradrine (MN-221) | MediciNova <i>San Diego, CA</i> | preterm labor (see also lung/respiratory) | Phase I (858) 373-1500 |
| Bijuva™ conjugated estrogens vaginal | Barr Laboratories <i>Pomona, NY</i> | vaginal atrophy | application submitted (800) 222-0190 |
| bremelanotide | Palatin Technologies <i>Cranbury, NJ</i> | female sexual dysfunction | Phase II (609) 495-2200 |
| CDB-2914 | HRA Pharma <i>New York, NY</i> | contraception (see also cancer) | Phase III (212) 679-2945 |
| Cenestin® conjugated estrogens oral | Duramed Pharmaceuticals <i>Cincinnati, OH</i> | vaginal atrophy (see also arthritis/musculoskeletal) | in clinical trials (513) 731-9900 |
| Cervarix® recombinant vaccine | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> MedImmune <i>Gaithersburg, MD</i> | prevention of human papilloma-virus infections | application submitted (888) 825-5249 (301) 398-0000 |
| Cetrotide® cetorelix | Aeterna Zentaris <i>Quebec, QC</i> | endometriosis | Phase III (418) 652-8525 |
| Chronodyne® terbutaline | Columbia Laboratories <i>Livingston, NJ</i> | endometriosis, female infertility | Phase II (866) 566-5636 |
| | | ----- dysmenorrhea | Phase I (866) 566-5636 |
| conjugated estrogens/ trimegestone | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | menopausal syndrome (see also arthritis/musculoskeletal) | Phase III (800) 934-5556 |
| corifollitropin alfa (ORG-36286) | Organon USA <i>Roseland, NJ</i> | infertility | Phase III (973) 325-4500 |
| CTV-05 | Osel <i>Santa Clara, CA</i> | bacterial vaginosis (see also kidney/urologic) | Phase II (408) 986-0012 |
| Cypat™ cyproterone acetate | Barr Laboratories <i>Pomona, NY</i> | hot flashes | Phase III (800) 222-0190 |
| CZEN-002 | Zengen <i>Woodland Hills, CA</i> | vulvovaginal candidiasis | Phase I (818) 887-8688 |

OBSTETRIC/GYNECOLOGIC CONDITIONS

| Product Name | Company | Indication | Development Status |
|---|---|---|---|
| elcometrine | Aveva Drug Delivery Systems Miramar, FL | contraception | Phase I |
| ERB-041 | Wyeth Pharmaceuticals Collegeville, PA | endometriosis (see also arthritis/musculoskeletal) | Phase II (800) 934-5556 |
| esmirtazapine (ORG-50081) | Organon Roseland, NJ | menopausal flushing | Phase III (973) 325-4500 |
| estradiol/ levonorgestrel continuous transdermal | Solvay Pharmaceuticals Marietta, GA | menopausal syndrome | Phase III (770) 578-9000 |
| estradiol/ norgestrol monophasic | Organon Roseland, NJ | contraception | Phase III (973) 325-5000 |
| estradiol/ norethisterone continuous transdermal | Pfizer New York, NY | menopausal syndrome | Phase III (860) 732-5156 |
| estradiol/progestin transdermal | Watson Pharmaceuticals Corona, CA | menopausal syndrome (see also arthritis/musculoskeletal) | application submitted (800) 249-5499 |
| estradiol transdermal | Elan Pharmaceuticals New York, NY | menopausal syndrome (see also arthritis/musculoskeletal) | Phase III (212) 407-5740 |
| estradiol/ trimegestone | Wyeth Pharmaceuticals Collegeville, PA | menopausal syndrome (see also arthritis/musculoskeletal) | Phase III (800) 934-5556 |
| Estredox™ E2CDS | IVAX Miami, FL | hot flashes, postmenopausal symptoms | Phase II (305) 757-6000 |
| ethinyl estradiol/ levonorgestrel transdermal | Agile Therapeutics San Jose, CA | contraception | Phase II (408) 284-4000 |
| Evamist™ estradiol | VIVUS Mountain View, CA | menopausal syndrome | application submitted (650) 934-5200 |
| Evista® raloxifene | Eli Lilly Indianapolis, IN | menopausal syndrome (see also cancer) | in clinical trials (800) 545-5979 |
| FE-999904 | Ferring Pharmaceuticals Parsippany, NJ | female infertility | Phase I (973) 796-1600 |
| Femprox® alprostadil topical | NexMed East Windsor, NJ | female sexual dysfunction | Phase II (609) 371-8123 |
| FP-1096 | KV Pharmaceutical St. Louis, MO | endometriosis | Phase III (314) 645-6600 |
| Gestiva™ hydroxy- progesterone | Cytec Prenatal Products Sunnyvale, CA | preterm labor | application submitted (888) 773-8376 |
| human papillomavirus vaccine | Biogen Idec Cambridge, MA | human papillomavirus infections | Phase I (617) 679-2000 |

OBSTETRIC/GYNECOLOGIC CONDITIONS

| Product Name | Company | Indication | Development Status |
|--|---|---|--------------------------------------|
| human papillomavirus vaccine | Novavax <i>Rockville, MD</i> | human papillomavirus infections | Phase II (240) 268-2000 |
| human papillomavirus vaccine | Virionics <i>Scottsdale, AZ</i> | human papillomavirus infections | Phase I (480) 254-5871 |
| Hyphanox™ itraconazole | Barrier Therapeutics <i>Princeton, NJ</i> | vulvovaginal candidiasis | Phase III (609) 945-1200 |
| Infergen® interferon alfacon-1 | Valeant Pharmaceuticals International <i>Aliso Viego, CA</i> | human papillomavirus infections | Phase III (800) 548-5100 |
| Intrinsa™ testosterone transdermal | Procter & Gamble Pharmaceuticals <i>Cincinnati, OH</i> | female sexual dysfunction | Phase III |
| IoGen™ iodine oral | Symbolion <i>Framingham, MA</i> | fibrocystic breast disorders | Phase III (508) 620-7676 |
| LeuProMaxx™ leuprorelin depot | Teva Parenteral Medicines <i>Irvine, CA</i> | endometriosis (see also cancer) | Phase II (949) 455-4700 |
| leuprorelin inhalation | Nektar Therapeutics <i>San Carlos, CA</i> | endometriosis | Phase I (650) 631-3100 |
| leuprorelin intranasal | Archimedes Pharma <i>Reading, UK</i> West Pharmaceuticals <i>Lionville, PA</i> | endometriosis | Phase II (610) 594-2900 |
| levtofisopam | Vela Pharmaceuticals <i>Ewing, NJ</i> | hot flashes | Phase I (609) 771-8660 |
| LibiGel™ testosterone topical | BioSante Pharmaceuticals <i>Lincolnshire, IL</i> | female sexual dysfunction | Phase III (847) 478-0500 |
| LibiGel E/T™ estradiol testosterone/ topical gel | BioSante Pharmaceuticals <i>Lincolnshire, IL</i> | female sexual dysfunction | Phase II (847) 478-0500 |
| lidocaine vaginal gel | Columbia Laboratories <i>Livingston, NJ</i> | dysmenorrhea | Phase II (866) 566-5636 |
| Livial® tibolone | Organon <i>Roseland, NJ</i> | female sexual dysfunction | in clinical trials (973) 325-4500 |
| Lunelle™ estradiol cypionate/medroxy-progesterone (subcutaneous) | Pfizer <i>New York, NY</i> | contraception | Phase II (860) 732-5156 |
| Lybrel™ levonorgestrel/EE continuous | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | premenstrual syndrome (see also psychiatric) | Phase III (800) 934-5556 |

OBSTETRIC/GYNECOLOGIC CONDITIONS

| Product Name | Company | Indication | Development Status |
|---|--|--|---|
| metreleptin | Amgen <i>Thousand Oaks, CA</i> | amenorrhea | Phase II (805) 447-1000 |
| MF-101 | Bionovo <i>Emeryville, CA</i> | menopausal syndrome | Phase II (510) 601-2000 |
| Misopess™ misoprostol controlled-release insert | CytoKine PharmaSciences <i>King of Prussia, PA</i> Xanodyne Pharmaceuticals <i>Florence, KY</i> | labor induction | Phase III (859) 371-6383 (610) 687-1776 |
| NBI-42902 | Neurocrine Biosciences <i>San Diego, CA</i> | endometriosis (see also cancer) | Phase I (858) 617-7600 |
| NBI-56418 | Neurocrine Biosciences <i>San Diego, CA</i> | endometriosis | Phase II (858) 617-7600 |
| Neurontin® gabapentin | Pfizer <i>New York, NY</i> | hot flashes (see also neurologic, psychiatric) | Phase II (860) 732-5756 |
| NMI-870 | NitroMed <i>Lexington, MA</i> | female sexual dysfunction | Phase II (781) 266-4000 |
| nomegestrol | Merck KGaA <i>Darmstadt, Germany</i> Theramex SAM <i>Monaco</i> | menopausal syndrome | in clinical trials |
| nonoxinol-9 liposomal | Novavax <i>Rockville, MD</i> | contraception | Phase I (240) 268-2000 |
| Norprolac® quinagolide | Ferring Pharmaceuticals <i>Parsippany, NJ</i> | hyperprolactinemia, prolactinoma | Phase II (973) 796-1600 |
| onercept (r-TBP-1) | EMD Serono <i>Rockland, MA</i> | endometriosis | Phase I (800) 283-8088 |
| Oporia™ lasofoxifene | Ligand Pharmaceuticals <i>San Diego, CA</i> Pfizer <i>New York, NY</i> | vaginal atrophy (see also arthritis/musculoskeletal, cancer) | application submitted (858) 550-7500 (860) 732-5156 |
| ospemifene | QuatRx Pharmaceuticals <i>Ann Arbor, MI</i> | vaginal atrophy | Phase III (734) 913-9900 |
| PH80 | Organon <i>Roseland, NJ</i> Pherin Pharmaceuticals <i>Redwood City, CA</i> | premenstrual syndrome | Phase II (973) 325-4500 (650) 568-1587 |
| Prexige® lumiracoxib | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | dysmenorrhea (see also arthritis/musculoskeletal) | Phase III (888) NOW-NOVA |
| Pristiq™ desvenlafaxine succinate (DVS-233) | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | menopausal syndrome (see also autoimmune, psychiatric) | application submitted (800) 934-5556 |
| Prochieve® progesterone 8% | Columbia Laboratories <i>Livingston, NJ</i> | preterm labor | Phase III (866) 566-5636 |

OBSTETRIC/GYNECOLOGIC CONDITIONS

| Product Name | Company | Indication | Development Status |
|--|---|--|--|
| R851 | Takeda Pharmaceuticals North America <i>Deerfield, IL</i> | human papillomavirus infections (see also cancer) | Phase II (224) 554-6500 |
| Revatio™ sildenafil | Pfizer <i>New York, NY</i> | female infertility | in clinical trials (860) 732-5156 |
| S-401-G | ProStrakan <i>Galashiels, UK</i> | menopausal syndrome | Phase II www.strakan.com |
| Savvy® 1% C31G vaginal gel | Biosyn <i>Philadelphia, PA</i> Cellegy Pharmaceuticals <i>Brisbane, CA</i> | contraception | Phase III (650) 616-2200 |
| SSR 126768 (ocytocine antagonist) | sanofi-aventis <i>Bridgewater, NJ</i> | preterm labor | Phase I (800) 633-1610 |
| TamoGel™ afimoxifene | Ascend Therapeutics <i>Herndon, VA</i> | breast disorders, breast pain (see also cancer) | Phase II (703) 471-4744 |
| testosterone progressive hydration vaginal tablet | Columbia Laboratories <i>Livingston, NJ</i> | menopausal syndrome (see also cancer) | Phase I (866) 566-5636 |
| testosterone vaginal (IVR) | Warner Chilcott <i>Rockaway, NJ</i> | female sexual dysfunction | in clinical trials (973) 442-3200 |
| Tostrelle™ testosterone gel | Cellegy Pharmaceuticals <i>Brisbane, CA</i> | female testosterone deficiency | Phase II (650) 616-2200 |
| Trelstar Depot® triptorelin | Watson Pharmaceuticals <i>Corona, CA</i> | endometriosis (see also cancer) | application submitted (800) 249-5499 |
| trimegestone | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | menopausal syndrome | Phase III (800) 934-5556 |
| trimegestone (transdermal) | Barr Pharmaceuticals <i>Pomona, NY</i> | contraception | in clinical trials (800) 222-0190 |
| Ushercell® cellulose sulfate | Polydex Pharmaceuticals <i>Toronto, ON</i> | contraception | Phase II (416) 755-2231 |
| | | venereal infections | Phase I (416) 755-2231 |
| Veldona® interferon alpha lozenge | Amarillo Biosciences <i>Amarillo, TX</i> | human papillomavirus infections (see also autoimmune) | Phase II (806) 376-1741 |
| verpasep caltespen (HspE7) vaccine | Nventa Biopharmaceuticals <i>San Diego, CA</i> Roche <i>Nutley, NJ</i> | human papillomavirus infections (see also cancer) | Phase II (858) 202-4900 (973) 235-5000 |
| WAY-195725 | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | dysmenorrhea (see also arthritis/musculoskeletal) | Phase I (800) 934-5556 |
| XP12B | Xanodyne Pharmaceuticals <i>Florence, KY</i> | menorrhagia | Phase III (859) 371-6383 |

PSYCHIATRIC DISORDERS

| Product Name | Company | Indication | Development Status |
|-----------------------------------|--|--|--|
| 561679 (CRF1 antagonist) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> Neurocrine Biosciences <i>San Diego, CA</i> | anxiety, depression (see also gastrointestinal) | Phase I (888) 825-5249 (858) 617-7600 |
| 588045 (5HT1 antagonist) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | anxiety, depression | Phase I (888) 825-5249 |
| 876008 (CRF1 antagonist) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> Neurocrine Biosciences <i>San Diego, CA</i> | anxiety, depression (see also gastrointestinal) | Phase II (888) 825-5249 (858) 617-7600 |
| Abilify™ aripiprazole | Bristol-Myers Squibb <i>Princeton, NJ</i> | unipolar depression | Phase III (212) 546-4000 |
| adatanserin | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | anxiety, depression | Phase II (800) 934-5556 |
| AFQ 056 | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | anxiety | Phase I (888) NOW-NOVA |
| agomelatine | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | depression | Phase III (888) NOW-NOVA |
| alprazolam inhalation | Alexza Pharmaceuticals <i>Palo Alto, CA</i> Symphony Allegro <i>Rockville, MD</i> | panic disorder | Phase II (650) 687-3900 |
| amibegron (SR 58611) | sanofi-aventis <i>Bridgewater, NJ</i> | anxiety, depression | Phase III (800) 633-1610 |
| AST-117 | Ariston Pharmaceuticals <i>Framingham, MA</i> | anxiety | in clinical trials (508) 665-4260 |
| AZD3783 | AstraZeneca <i>Wilmington, DE</i> | anxiety, depression | Phase I (800) 236-9933 |
| casopitant (NK1 antagonist) | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | anxiety, depression (see also kidney/urologic) | Phase II (888) 825-5249 |
| Corlux™ mifepristone | Corcept Therapeutics <i>Menlo Park, CA</i> | depression (see also cancer, neurologic) | Phase III (650) 327-3270 |
| DOV 21947 | DOV Pharmaceutical <i>Hackensack, NJ</i> | depression | Phase I (201) 968-0980 |
| DOV 216303 | DOV Pharmaceutical <i>Hackensack, NJ</i> | depression | Phase II (201) 968-0980 |
| dronabinol (inhalation) | United Therapeutics <i>Silver Spring, MD</i> | anorexia nervosa | Phase I (301) 608-9292 |
| elzasonan | Pfizer <i>New York, NY</i> | depression | Phase II (860) 732-5156 |
| Gabitril® tiagabine HCl | Cephalon <i>West Chester, PA</i> | anxiety | Phase III (610) 344-0200 |

PSYCHIATRIC DISORDERS

| Product Name | Company | Indication | Development Status |
|---|---|---|---|
| Inversine [®] mecamylamine | Targacept Winston-Salem, NC | depression | Phase II (336) 480-2100 |
| L-759274 | Merck Whitehouse Station, NJ | depression | Phase III (800) 672-6372 |
| Lamactil [®] lamotrigine | GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC | depression | in clinical trials (888) 825-5249 |
| Lexapro [™] escitalopram | Forest Laboratories New York, NY | panic disorder | application submitted (800) 947-5227 |
| | | premenstrual dysphoric disorder | in clinical trials (800) 947-5227 |
| lorazepam intranasal | Intranasal Therapeutics Montvale, NJ | anxiety | Phase I (859) 252-5080 |
| Lybrel [™] levonorgestrel/EE | Wyeth Pharmaceuticals Collegeville, PA | premenstrual dysphoric disorder (see also obstetric/gynecologic) | Phase III (800) 934-5556 |
| Lyrica [®] pregabalin | Pfizer New York, NY | generalized anxiety disorder | application submitted (860) 732-5156 |
| midazolam intranasal | Intranasal Therapeutics Montvale, NJ | anxiety | Phase I (859) 252-5080 |
| milnacipran | Cypress Biosciences San Diego, CA Forest Laboratories New York, NY | depression (see also autoimmune) | Phase III (858) 452-2323 (800) 947-5227 |
| MN-305 | MediciNova San Diego, CA | generalized anxiety disorder | Phase II (858) 373-1500 |
| nemifitide | Innapharma Park Ridge, NJ | depression | Phase II (201) 505-1300 |
| Neurontin [®] gabapentin | Pfizer New York, NY | anxiety (see also neurologic, obstetric/gynecologic) | in clinical trials (860) 732-5156 |
| NGD 913 | Neurogen Branford, CT Pfizer New York, NY | anxiety | Phase II (203) 488-8201 (860) 732-5156 |
| ONO 2333Ms | Ono Pharma USA Lawrenceville, NJ | anxiety, depression | Phase I |
| ORG 34517 | Organon Roseland, NJ | depression | Phase II (973) 325-4500 |
| pagoclone | Indevus Pharmaceuticals Lexington, MA | panic disorder | Phase III (781) 861-8444 |
| | | generalized anxiety disorder | Phase II (781) 861-8444 |
| pardoprunox | Solvay Marietta, GA | depression, panic disorder | Phase II (770) 578-9000 |

PSYCHIATRIC DISORDERS

| Product Name | Company | Indication | Development Status |
|--|---|--|---|
| PD-332334 | Pfizer <i>New York, NY</i> | generalized anxiety disorder | Phase II (860) 732-5156 |
| pexacerfont (CRF receptor-1 antagonist) | Bristol-Myers Squibb <i>Princeton, NJ</i> | depression | Phase II (212) 546-4000 |
| PF-572778 | Pfizer <i>New York, NY</i> | generalized anxiety disorder | Phase I (860) 732-5156 |
| PH 94B | Pherin Pharmaceuticals <i>Redwood City, CA</i> | anxiety | Phase II (650) 568-1587 |
| Pristiq™ desvenlafaxine | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | depression (see also autoimmune, obstetric/gynecologic) | application submitted (800) 934-5556 |
| Prozac® fluoxetine | Eli Lilly <i>Indianapolis, IN</i> | panic disorder | Phase III (800) 545-5979 |
| PRX-00023 | EPIX Pharmaceuticals <i>Lexington, MA</i> | depression | Phase II (781) 761-7600 |
| RC-1291 | Sapphire Therapeutics <i>Bridgewater, NJ</i> | anorexia | Phase II (908) 231-1435 |
| saredutant (SR 48968) | sanofi-aventis <i>Bridgewater, NJ</i> | anxiety, depression | Phase III (800) 633-1610 |
| SAX-187 | Wyeth Pharmaceuticals <i>Collegeville, PA</i> | anxiety | Phase I (800) 934-5556 |
| SEP-225289 | Sepracor <i>Marlborough, MA</i> | depression | Phase I (508) 481-6700 |
| SEP-227162 | Sepracor <i>Marlborough, MA</i> | depression | Phase I (508) 481-6700 |
| Seroquel® quetiapine fumarate | AstraZeneca <i>Wilmington, DE</i> | bipolar maintenance | Phase III (800) 236-9933 |
| Seroquel® SR quetiapine fumarate (sustained-release) | AstraZeneca <i>Wilmington, DE</i> | bipolar depression, bipolar mania, generalized anxiety disorder, major depressive disorder | Phase III (800) 236-9933 |
| SNEC 2 | Lundbeck Research USA <i>Paramus, NJ</i> | depression | Phase I (201) 261-1331 |
| SSR 101010 (FAAH inhibitor) | sanofi-aventis <i>Bridgewater, NJ</i> | anxiety, depression | Phase I (800) 633-1610 |
| SSR 125543 (CRF1 antagonist) | sanofi-aventis <i>Bridgewater, NJ</i> | anxiety, depression | Phase I (800) 633-1610 |
| SSR 149415 (V1B antagonist) | sanofi-aventis <i>Bridgewater, NJ</i> | anxiety, depression | Phase II (800) 633-1610 |
| SSR 411298 (FAAH inhibitor) | sanofi-aventis <i>Bridgewater, NJ</i> | anxiety, depression | Phase I (800) 633-1610 |
| Symbyax™ olanzapine/ fluoxetine | Eli Lilly <i>Indianapolis, IN</i> | depression | application submitted (800) 545-5979 |

PSYCHIATRIC DISORDERS

| Product Name | Company | Indication | Development Status |
|-------------------------------|---|--|---|
| talaglumeted | Eli Lilly <i>Indianapolis, IN</i> | generalized anxiety disorder | Phase III (800) 545-5979 |
| Tyrima™ CX 157 | CeNeRx BioPharma <i>Cary, NC</i> | anxiety, depression | Phase I (866) 287-2622 |
| Variza™ gepirone ER | GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> | major depressive disorder | application submitted (888) 825-5249 |
| VEC-162 | Vanda Pharmaceuticals <i>Rockville, MD</i> | depression | in clinical trials (240) 599-4500 |
| Vestra® reboxetine | Pfizer <i>New York, NY</i> | depression (see also kidney/urologic) | application submitted (860) 732-5156 |
| vilazodone | Clinical Data <i>Newton, MA</i> | depression | Phase III (617) 527-9933 |
| VPI-013 (OPC-14523) | Otsuka America <i>Gaithersburg, MD</i> Vela Pharmaceuticals <i>Ewing, NJ</i> | depression | Phase II (609) 771-8660 |
| YKP 10A | SK Bio-Pharmaceuticals <i>Fairlawn, NJ</i> | depression | Phase II (201) 421-3800 |
| YKP 3089 | SK Bio-Pharmaceuticals <i>Fairlawn, NJ</i> | anxiety | Phase I (201) 421-3800 |
| Zoloft® sertraline | Pfizer <i>New York, NY</i> | generalized anxiety disorder | in clinical trials (860) 732-5156 |

SEPSIS

| Product Name | Company | Indication | Development Status |
|--|---|----------------------|-----------------------------|
| afelimomab | Abbott Laboratories <i>Abbott Park, IL</i> | sepsis, septic shock | Phase III (847) 937-6100 |
| CytoFab™ anti-TNF alpha polyclonal antibody | AstraZeneca <i>Wilmington, DE</i> | septic shock | Phase II (800) 236-9933 |
| eritoran | Eisai <i>Ridgefield Park, NJ</i> | septic shock | Phase III (888) 274-2378 |
| NOX-100 | Medinox <i>Carlsbad, CA</i> | septic shock | Phase II (760) 603-8989 |
| PF-03491390 | Pfizer <i>New York, NY</i> | septic shock | Phase I (860) 732-5156 |
| PMX-622 | Novartis Pharmaceuticals <i>East Hanover, NJ</i> | septic shock | Phase II (888) NOW-NOVA |
| pyridoxalated hemoglobin polyoxyethylene | Curacyte <i>Chapel Hill, NC</i> | septic shock | Phase III (919) 405-4002 |
| TAK-242 | Takeda Pharmaceuticals North America <i>Deerfield, IL</i> | septic shock | Phase III (224) 554-6500 |

OTHER

| Product Name | Company | Indication | Development Status |
|--|--|-------------------|---|
| Accretropin™ somatotropin | Cangene <i>Winnipeg, MB</i> | Turner's syndrome | application submitted (204) 275-4200 |
| AMG 114 | Amgen <i>Thousand Oaks, CA</i> | anemia | Phase I (805) 447-1000 |
| CNTO 528 | Centocor <i>Horsham, PA</i> | anemia | Phase I (610) 651-6000 |
| ferumoxytol | Advanced Magnetics <i>Cambridge, MA</i> | anemia | Phase III (617) 497-2070 |
| FG-2216 | FibroGen <i>South San Francisco, CA</i> | anemia | Phase II (650) 866-7200 |
| FG-4592 | FibroGen <i>South San Francisco, CA</i> | anemia | Phase I (650) 866-7200 |
| Genotropin® somatotropin | Pfizer <i>New York, NY</i> | Turner's syndrome | application submitted (860) 732-5156 |
| Hematide™ erythropoietin mimetic | Affymax <i>Palo Alto, CA</i> | anemia | Phase II (650) 812-8700 |
| Hemopure® hemoglobin glutamer-250 (bovine) | Biopure <i>Cambridge, MA</i> | anemia | application submitted (617) 234-6500 |
| R744 (continuous erythropoietin receptor activator) | Roche <i>Nutley, NJ</i> | renal anemia | application submitted (973) 235-5000 |
| recombinant erythropoietin | Syntonix Pharmaceuticals <i>Waltham, MA</i> | anemia | Phase I (781) 547-6000 |
| RF 1010 | SuperGen <i>Dublin, CA</i> | anemia | Phase II (925) 560-0100 |

The content of this report has been obtained through public, government and industry sources, and the Adis "R&D Insight" database based on the latest information. **Report current as of July 16, 2007.** The information in this report may not be comprehensive. For more specific information about a particular product, contact the individual company directly or go to www.clinicaltrials.gov. The entire series of *Medicines in Development* is available on PhRMA's web site.

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GLOSSARY

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

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

chlamydial infections—Chlamydiae are a group of microorganisms that cause various infectious diseases in humans and animals. The most important impact of the strain *Chlamydia trachomatis* is its role as a cause of nonspecific urethritis, or nongonococcal genital infection. This is the most common sexually transmitted disease in the United States.

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

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

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

genital herpes—A common, contagious, viral disease that exists in two forms—HSV1 (herpes simplex virus, type 1) and HSV2 (type 2). HSV1 is usually

associated with infections of the lips, mouth and face. HSV2 is often associated with genital infections and infections acquired by babies at birth.

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

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

incontinence, urinary—Uncontrollable, involuntary urination, often due to injury or disease of the urinary tract.

Stress incontinence refers to the involuntary escape of a small amount of urine when a person coughs, laughs, picks up a heavy package or moves excessively.

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

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

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

nephritis—Inflammation of the kidneys.

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

osteoporosis—The most common metabolic bone disease in older people in which a reduction in bone mass

leads to fractures, especially of the vertebrae, hips and wrists.

Phase I—Safety testing and pharmacological profiling in humans.

Phase II—Effectiveness and safety testing in humans.

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

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

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

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

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

Sjogren's syndrome—A condition in which the eyes, mouth and vagina become excessively dry. It tends to occur with autoimmune disorders, but the exact cause is unknown. Most sufferers are middle-aged, postmenopausal women.

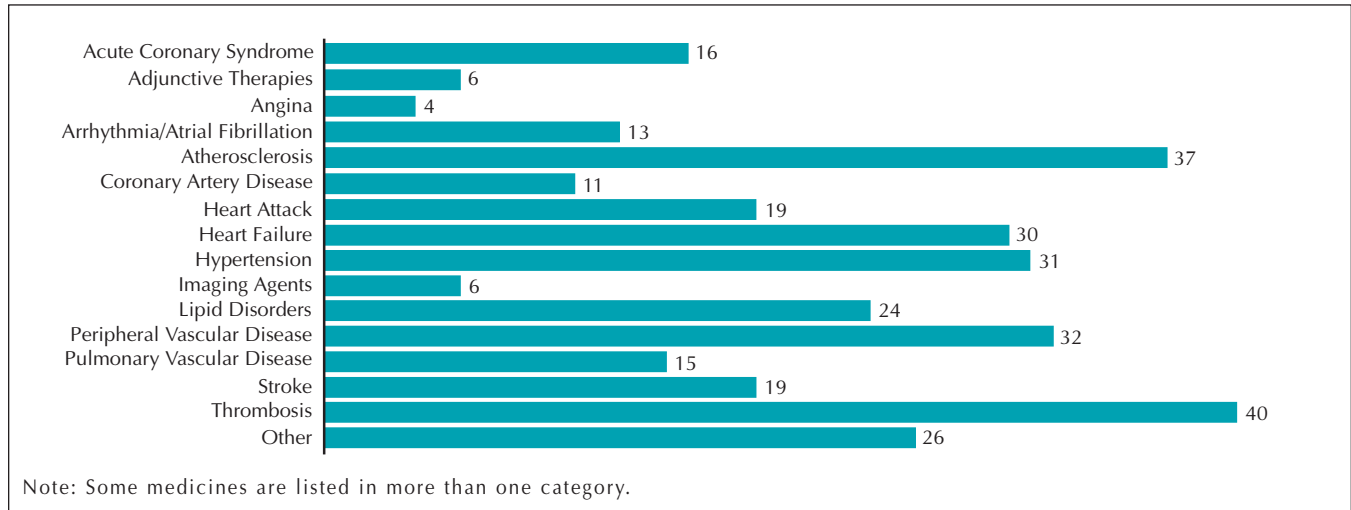
systemic lupus erythematosus—A chronic autoimmune disorder, affecting many systems of the body, including the kidneys and brain.

uterine fibroids—Benign masses of the uterus that grow slowly within the uterine wall and vary in size from that of a pea to a grapefruit. Hysterectomy is often required for multiple fibroids that cause serious symptoms and complications.

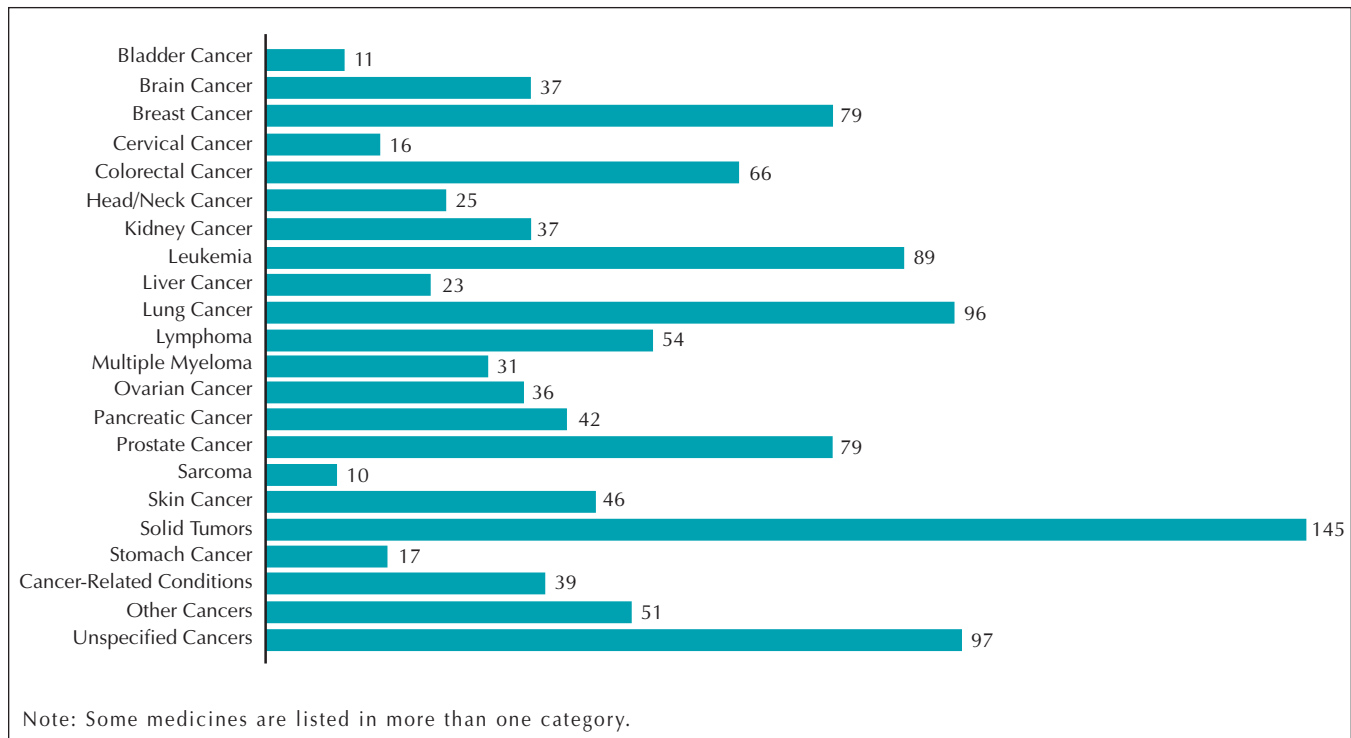
MORE THAN 1,500 MEDICINES IN DEVELOPMENT FOR THE THREE LEADING CAUSES OF DEATH FOR AMERICAN WOMEN

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

MEDICINES IN DEVELOPMENT FOR HEART DISEASE AND STROKE



MEDICINES/VACCINES IN DEVELOPMENT FOR CANCER



FACTS ABOUT DISEASES/CONDITIONS AFFECTING WOMEN IN THE UNITED STATES

Ten Leading Causes of Death in Women, 2003

| | |
|--|-------------------------------------|
| 1. Heart Disease (348,994) | 6. Diabetes (38,781) |
| 2. Cancer (268,912) | 7. Accidents (38,745) |
| 3. Cerebrovascular Diseases (96,263) | 8. Influenza and Pneumonia (36,385) |
| 4. Chronic Lower Respiratory Diseases (65,668) | 9. Nephritis (21,972) |
| 5. Alzheimer's Disease (45,122) | 10. Septicemia (19,082) |

Source: *National Vital Statistics Report*, Vol. 55, No. 10, March 15, 2007. National Center for Health Statistics. (Number in parentheses is the number of total deaths in women.)

Overview¹

- In 2004, men were more likely than women to report being in excellent or very good health (62.9 percent versus 59.9 percent); that was true in every racial and ethnic group.
 - Self-reported health status declines with age: 70.8 percent of women ages 18 to 44 reported excellent or very good health, compared with 55.7 percent of those ages 45 to 64, 42.7 percent of those ages 65 to 74, and 31.5 percent of those age 75 and older.
 - In 2004, just over 14 percent of the U.S. population reported having at least one condition that limited their ability to perform one or more common activities (e.g., walking up stairs, grasping small objects, carrying groceries). Women were more likely to report being limited in their activities than men (15.4 percent versus 12.8 percent).
-

Arthritis/Musculoskeletal Disorders

- Of the 70 million Americans estimated to have some form of **arthritis** in 2002, 41 million were women (58.6 percent) and 28.9 million were men (41.3 percent).²
 - Considered the leading cause of disability in older people, **osteoarthritis (OA)** affects more than 21 million Americans. OA usually develops in people over the age of 50. Women comprise about 63.5 percent of OA cases in Americans age 60 and older.²
 - **Osteoporosis** is a major public health threat for an estimated 44 million Americans, 80 percent of whom are women. Today, 10 million people already have the disease, and 34 million more have low bone mass, placing them at increased risk for osteoporosis.³
 - The estimated cost of **arthritis** to the economy in 2000 was nearly \$125 billion, including \$42.6 billion in medical expenses and \$82.2 billion in lost productivity.²
-

Autoimmune Diseases

- **Autoimmune diseases** are a family of more than 80 chronic and often disabling illnesses that collectively affect up to 23.5 million people in this country. Because most of these diseases disproportionately afflict women and are among the leading causes of death for young and middle-aged women, they impose a heavy burden on patients' families and on society.⁴
- More than 1 million Americans have **chronic fatigue syndrome (CFS)**, which strikes more people than **multiple sclerosis, lupus, lung cancer, or ovarian cancer**. CFS occurs four times more frequently in women than in men. CFS is at least as common among African Americans and Hispanics as it is among Caucasians.⁵
- Approximately 2 percent of the U. S. population has **fibromyalgia**, which affects predominantly women (more than 80 percent) between the ages of 35 and 55. It can occur independently or along with other diseases, such as **systemic lupus or rheumatoid arthritis**.⁶

FACTS ABOUT DISEASES/CONDITIONS AFFECTING WOMEN IN THE UNITED STATES

Autoimmune Diseases (continued)

- **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.⁷ African-American women are three times more likely to get lupus than Caucasian women, and lupus is twice as prevalent among Asian-American and Hispanic women as it is among Caucasian women.⁸
 - Between 1979 and 1989, death rates from **lupus** increased between 60 percent and 70 percent. Each year during that period, lupus death rates were more than five times higher for women than for men and more than three times higher for African Americans than for Caucasians. For African-American women between the ages of 45 and 64, lupus death rates during that time increased nearly 70 percent.⁸
 - Some 400,000 Americans acknowledge having **multiple sclerosis (MS)**, which strikes two to three times as many women as men. Each week, about 200 people are newly diagnosed with MS, usually between the ages of 20 and 50.⁹
 - Between 5.8 million and 7.5 million Americans have **psoriasis**. The prevalence of psoriasis in African Americans is 1.3 percent and in Caucasians 2.5 percent. The overall costs of treating the disease may exceed \$3 billion annually.¹⁰
 - **Sjogren's syndrome** is one of the most prevalent autoimmune disorders, striking as many as 4 million Americans, of whom nine out of 10 are women. About half of Sjogren's cases occur along with another connective tissue disease, primarily **rheumatoid arthritis, systemic lupus, scleroderma, and polymyositis/dermatomyositis**.¹¹
 - The estimated national direct care expenditures (including hospitals, nursing homes, and outpatient services for **osteoporotic fractures** are \$18 billion annually (in 2002 dollars), and costs are rising.³
-

Cancer¹²

- Women have a lifetime risk of a little more than 1 in 3 of developing cancer. An estimated 678,060 women will be diagnosed with some form of cancer in 2007, and an estimated 270,100 will die from cancer this year.
 - An estimated 178,480 women will be diagnosed with invasive **breast cancer** this year. It is the most frequently diagnosed cancer in women. After continuously increasing for more than two decades, female breast cancer incidence rates leveled off from 2001-2003. An estimated 40,460 women will die from it in 2007.
 - An estimated 11,150 new cases of invasive **cervical cancer** will be diagnosed in 2007. Incidence rates have decreased steadily over the past several decades in both white and African-American women. An estimated 3,670 women will die from cervical cancer this year.
 - An estimated 39,080 new cases of **endometrial cancer** (cancer of the uterine corpus) will be diagnosed in 2007, and an estimated 7,400 women are expected to die from it.
 - Women will account for 98,620 of the 213,380 new cases of **lung cancer** diagnosed in 2007. While the incidence rate is falling in men (from a high of 102 cases per 100,000 in 1984 to 78.5 in 2003), in women the rate is leveling out after a long period of increase. Even though lung cancer death rates have continued to decline significantly in men, and women's rates are approaching a plateau after increasing for decades, lung cancer still accounts for the most cancer-related deaths in both men and women. Of the estimated 160,390 lung cancer deaths expected in 2007, 70,880 will be in women and 89,510 will be in men.
 - An estimated 22,430 new cases of **ovarian cancer** will be diagnosed in 2007. It accounts for about 3 percent of all cancers among women and ranks second among gynecologic cancers. An estimated 15,280 women will die from ovarian cancer this year.
 - The estimated overall costs for **cancer** in 2006 were \$206.3 billion.
-

Diabetes⁵

- From 1990 to 1998, the prevalence of **diabetes** increased almost one-third for both women and men. Today, approximately 9.7 million women over age 20 have **diabetes**, but about one-third of them do not know it. About 86,192 females younger than age 20 have type 1 diabetes.

FACTS ABOUT DISEASES/CONDITIONS AFFECTING WOMEN IN THE UNITED STATES

Diabetes⁵ (continued)

- Women in minority racial and ethnic groups are the hardest hit by **type 2 diabetes**—the prevalence is two to four times higher among African-American, Hispanic, American Indian, and Asian-Pacific Islander women than among white women.
 - **Diabetes** is a leading cause of death among middle-aged American women (ages 45-64). **Coronary heart disease** is an important cause of illness among middle-aged women with diabetes—rates are three to seven times higher among women with diabetes in this age group than among those without diabetes.
-

Eye Disorders

- **Cataract** affects nearly 20.5 million Americans age 40 and older, or about one in every six people in this age range. By age 80, more than half of all Americans have cataract. It is slightly more common in women than in men and also affects whites somewhat more frequently than other races, particularly with increasing age.¹³
 - About 6 million women and 3 million men have moderate or severe symptoms of **dry eye syndrome**, and another 20 million to 30 million people have mild cases of the disorder. Dry eye syndrome affects women two to three times more than men.¹⁴
 - **Glaucoma** affects more than 2.2 million Americans age 40 and older, or about 1.9 percent of that population. In general, glaucoma is more common in African Americans, Hispanics, and the elderly. Glaucoma appears to be more common initially in women, but by age 65, prevalence becomes more comparable between the sexes. In the 65-69 age group, the prevalence rate for white females is about 1.6 percent, while in African-American females the rate is three times higher at 4.8 percent. For those age 80 and older, glaucoma affects more than 10 percent of African-American men and Hispanic women.¹³
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Gastrointestinal Disorders

- Second only to the common cold in causing days missed from work, **irritable bowel syndrome (IBS)** may affect up to 20 percent of Americans, or some 54 million people. Three times more women than men suffer from IBS.¹⁵
 - Some \$30 billion is spent annually on **IBS**, excluding prescription and over-the-counter medications.¹⁶
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Heart Disease and Stroke

- One in three women has some form of **cardiovascular disease (CVD)**—the leading cause of death among women in the United States.¹⁷ Almost twice as many women died of **heart disease** and **stroke** than from all types of **cancer** combined in the year 2000. Most women are unaware of their risk for heart disease, and they fear breast cancer more than any other disease. CVD kills roughly 10 times more women each year than breast cancer.²
- Among women age 20 and older, the following have **angina**: 3.9 percent of non-Hispanic whites, 4.3 percent of non-Hispanic blacks, and 3.3 percent of Mexican Americans.¹⁷
- About 7.2 million women alive today have a history of **coronary heart disease (myocardial infarction [heart attack], angina pectoris, or both)**. Of that population, 3 million have a history of heart attack. This year, some 345,000 women will have a heart attack. About 23 percent of women age 40 and older who have an initial recognized heart attack die within a year compared with 18 percent of men. In part, because women have heart attacks at older ages than men do, they're more likely to die from them within a few weeks.¹⁷
- The annual rates per 1,000 population of white women for new **heart failure** events are: 8.2 for ages 65-74, 19.8 for ages 75-84, and 45.6 for age 85 and older. For African-American women, those rates are: 14.2 for ages 65-74, 25.5 for ages 75-84, and 44 for age 85 and older. In 2004, 35,199 women died of heart failure, representing 61 percent of deaths from the disease.¹⁷

FACTS ABOUT DISEASES/CONDITIONS AFFECTING WOMEN IN THE UNITED STATES

Heart Disease and Stroke (continued)

- Among women age 20 and older, the following have **high blood pressure (hypertension)**: 31.9 percent of non-Hispanic whites, 46.6 percent of non-Hispanic blacks, and 31.4 percent of Mexican Americans. Compared with white women, African-American women have an 85 percent higher rate of ambulatory medical care visits for hypertension.¹⁷
- An estimated 3.3 million female stroke survivors are alive today. Each year, about 40,000 more women than men have **strokes**, and more than 60 percent of total stroke deaths occur in women. Some 14 percent of people who survive a first stroke will have another one within a year.¹⁷

Kidney/Urologic Disorders

- **Interstitial cystitis (IC)** is far more common in women than in men—of the estimated 1 million Americans with IC, up to 90 percent are women.¹⁸
- **Overactive bladder (OAB)** affects more than 34 million Americans, including one in five adults over age 40, and nearly twice as many women as men.¹⁹
- Women suffer from **urinary incontinence (UI)** at twice the rate of men.²⁰ UI affects an estimated 38 percent of women age 60 and older, and it affects about 17 percent of men in that age group.¹⁸
- **Urinary tract infections (UTIs)** are the second most common type of infection in the body. They account for about 8.3 million doctor visits annually. Women are especially prone to UTIs—one woman in five develops a UTI during her lifetime. Nearly 20 percent of women who have a UTI will have another one, and 30 percent of those women will have yet another. Of the last group, 80 percent will have recurrences.¹⁸
- A recent estimate suggests that the annual direct costs for **UI** are more than \$16 billion, with 70 percent of the costs for women attributed to “routine care” (i.e., increased laundry, incontinence pads/briefs, nursing care). Total direct and indirect costs have been estimated at \$26.3 billion, or \$3,565 per individual age 65 and older with UI. That includes more than \$1 billion spent annually on adult disposable products and about \$1.8 billion spent on the costs associated with the medical consequences and complications of **OAB**. With the aging of the U.S. population, the public health costs will significantly increase.²¹
- In 2000, \$3.5 billion was spent on the evaluation and treatment of **UTIs**.¹⁸

Lung/Respiratory Disorders²²

- Females have had consistently higher lifetime prevalence rates of **asthma** than have males. In 2004, females were about 6 percent more likely than males to ever have been diagnosed with asthma. That year, 8.9 million males and 11.6 million females had asthma. The prevalence rate in females (78.8 per 1,000 people) was 24 percent greater than the rate in males (63.4 per 1,000 people) overall and 68 percent greater in female adults over age 18 (49.1 per 1,000 vs. 82.5 per 1,000).
- Females tend to have consistently higher **asthma attack** prevalence rates than males. In 2004, 6.5 million females (44.3 per 1,000) had an asthma attack compared to 5.1 million males (36.7 per 1,000).
- In 2003, 4,099 people died of **asthma**, and 64 percent of them were women. The female death rate was 80 percent greater than the male death rate. The age-adjusted death rate for asthma in the African-American population (2.7 per 100,000) was more than double the rate in the white population (1.2 per 100,000). African-American women had the highest mortality rate due to asthma in 2003 (2.9 per 100,000).
- In 2004, **asthma** caused an estimated 14 million lost school days for children and 14.5 million lost work days for adults. Asthma ranks within the top 10 prevalent conditions causing limitation of activity.
- In 2004, the direct health care costs for **asthma** were \$11.5 billion; indirect costs (lost productivity) added another \$4.6 billion for a total of \$16.1 billion. Prescription drugs represented the largest single direct medical expenditure at \$5 billion. The value of lost productivity due to death represented the largest single indirect cost at \$1.7 billion.

FACTS ABOUT DISEASES/CONDITIONS AFFECTING WOMEN IN THE UNITED STATES

Neurologic Disorders

- Today, more than 5 million people in the United States are living with **Alzheimer's disease**; 4.9 million of them are age 65 and older. Every 72 seconds, someone develops Alzheimer's; by mid-century, someone will develop the disease every 33 seconds. In 2000, an estimated 411,000 new cases of Alzheimer's were diagnosed. That number is expected to increase to 959,000 new cases a year by 2050.²³
- In 1991, only 14,112 death certificates recorded **Alzheimer's** as the underlying cause. From 2000-2004, deaths from Alzheimer's disease increased by 32.8 percent, while **heart disease**, the leading cause of death, decreased by 8 percent.²³
- Because women live longer than men, **Alzheimer's** disproportionately affects women. Women comprise 72 percent of the U.S. population age 85 and older, and nearly half of that group has Alzheimer's disease. A female born in 1994 has a 1 in 6 chance of developing Alzheimer's if she lives to an average life expectancy of 80 years—a greater lifetime risk than for **breast cancer**.²³
- Eighty percent of caregivers are women, usually the wife, daughter or daughter-in-law of the person with **Alzheimer's**. One study found that daughters provided an average of seven hours of care per week, while sons provided an average of four hours of care per week.²³
- Of the estimated 28 million **migraine** sufferers, 75 percent, or about 21 million, are women. More than 157 million workdays are lost each year due to migraines. Missed work or reduced productivity due to migraines costs the economy \$13 billion annually.²⁴
- The direct and indirect costs of **Alzheimer's** and other **dementias** amount to more than \$148 billion annually.²³

Obstetric/Gynecologic Conditions

- In 2005, 62 million American women were in their childbearing years (15–44), and 62 percent of them were using a **contraceptive** method. Another 31 percent of those women do not need a contraceptive because they are infertile; pregnant, postpartum, or trying to become pregnant; have never had intercourse; or are not sexually active. Among the 42 million fertile, sexually active women who do not want to become pregnant, 89 percent are practicing contraception. For women younger than age 30, birth control pills are the leading method. By age 35, more women rely on sterilization.²⁵
- **Dysmenorrhea** (severe menstrual pain) is the leading cause of lost time from school and work among women in their teens and 20s.²⁶
- An estimated 10 percent–20 percent of American women—or 5.5 million women and girls—of childbearing age have **endometriosis**. It is more common than **AIDS**, more common than **cancer**, and one of the three major causes of female **infertility**.²⁷
- **Female sexual dysfunction** affects approximately 43 percent of women. There is evidence that the disorder happens mostly after **menopause** when hormone production drops and vascular conditions are more common.²⁸
- **Fibrocystic** changes are the most common cause of **breast lumps** in women ages 30 to 50. At least 60 percent of the women in their reproductive years have “lumpy” breasts as a result of these non-cancerous conditions.²⁹
- Nationwide, at least 45 million people ages 12 and older, or 1 out of 5 adolescents and adults, have had **genital herpes (herpes simplex virus type two)**. It is more common in women than men, infecting approximately 1 out of 4 women versus 1 out of 5 men.⁵
- **Hot flashes** are, by far, the most common symptom of **menopause**, with about 75 percent of women experiencing them. For 80 percent of women, hot flashes occur for two years or less, but for a small percentage of women hot flashes last for more than two years.²⁷

FACTS ABOUT DISEASES/CONDITIONS AFFECTING WOMEN IN THE UNITED STATES

Obstetric/Gynecologic Conditions (continued)

- Approximately 20 million people are currently infected with **human papillomavirus (HPV)**, and more than 6 million Americans contract a new genital HPV infection each year. There are more than 100 different types of HPV, and some types cause **genital warts**. At least half of sexually active men and women acquire genital HPV infection at some point in their lives, and by age 50, at least 80 percent of women will have acquired it.⁵
- Aside from AIDS, the most common and serious complication of **sexually transmitted diseases** among women is **pelvic inflammatory disease (PID)**. In the United States, more than 1 million women experience an episode of acute PID each year, with teenagers having the highest rate of infection. More than 100,000 women become infertile each year as a result of PID.²⁷ The annual estimated costs associated with PID and its consequences exceed \$4 billion.³⁰
- The United States has the highest rates of **sexually transmitted diseases (STDs)** in the industrialized world.²¹ More than 65 million people have an incurable STD, and more than 13 million people are infected each year.⁵
- **Uterine fibroids** are the most common non-cancerous tumors in women of childbearing age. African-American women are three to five times more likely to have fibroids than white women. Fibroids are the cause of more than 200,000 hysterectomies every year.³¹ The costs associated with hysterectomy are estimated at \$5 billion annually.³⁰
- Up to 40 percent of **postmenopausal** women have symptoms of **vaginal atrophy**. Despite the prevalence of symptoms, only about 25 percent of symptomatic women seek medical attention.³²

Psychiatric Disorders

- **Anxiety disorders**, which include **panic disorder**, **obsessive-compulsive disorder (OCD)**, **post-traumatic stress disorder (PTSD)**, **phobias**, and **generalized anxiety disorder**, affect an estimated 13.3 percent of Americans ages 18 to 54 in a given year or about 19.1 million adults in this age group. Women outnumber men in each illness category, except for OCD and social phobia, for which both sexes have an equal likelihood of being affected.³³
- **Bipolar disorder** affects approximately 5.7 million adults, or about 2.6 percent of the U.S. population age 18 and older in a given year. Men and women are equally likely to develop the disorder.³³
- **Major depression** is the leading cause of disease burden among females ages 5 and older worldwide. **Major depressive disorder** is the leading cause of disability in the United States for ages 15–44. It affects some 14.8 million adults or about 6.7 percent of the U.S. population age 18 and older in a given year. The disorder is more prevalent in women than in men.³³
- The female risk of developing **post-traumatic stress disorder (PTSD)** following trauma is twice that of males. Females also are more likely to develop long-term PTSD than males and have higher rates of co-occurring medical and psychiatric problems than males with PTSD.³³
- About 75 percent of women of childbearing age have some premenstrual syndrome (PMS) problems. Up to 10 percent of women in that age group have a severe form of PMS called **premenstrual dysphoric disorder**.³²

Sepsis

- Every year, severe **sepsis** strikes an estimated 750,000 people in the United States. The annual incidence rate of sepsis has increased 91.3 percent over the last 10 years, and it is expected to rise to 1 million by the end of the decade as the population ages.³⁴
- **Septicemia**, which is a state of **sepsis**, killed 19,082 females and 14,987 males in 2003.³⁵
- This year, severe **sepsis** is expected to take 215,000 lives. Every hour, 25 people in the United States die from severe sepsis. One of every three patients who develop severe sepsis will die within a month. Severe sepsis, the leading cause of death in the non-coronary intensive care unit, takes more lives than **breast**, **colorectal**, **pancreatic**, and **prostate cancers** combined.³⁴

FACTS ABOUT DISEASES/CONDITIONS AFFECTING WOMEN IN THE UNITED STATES

Sepsis (continued)

- Treating patients with severe **sepsis** costs U.S. hospitals nearly \$17 billion a year.³⁶
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Sources:

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3. National Osteoporosis Foundation (www.nof.org)
4. National Institute of Allergy and Infectious Diseases, National Institutes of Health (www.niaid.nih.gov)
5. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (www.cdc.gov)
6. Medicine Net, Inc. (www.medicinenet.com)
7. Lupus Foundation of America (www.lupus.org)
8. Lupus Research Institute (www.lupusresearchinstitute.org)
9. National Multiple Sclerosis Society (www.nationalmssociety.org)
10. National Psoriasis Foundation (www.psoriasis.org)
11. Sjogren's Syndrome Foundation (www.sjogrens.org)
12. American Cancer Society (www.cancer.org)
13. Prevent Blindness America (www.preventblindness.org)
14. National Women's Health Resource Center (www.healthywomen.org)
15. U.S. Food and Drug Administration, U.S. Department of Health and Human Services (www.fda.gov)
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17. American Heart Association (www.americanheart.org)
18. National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health (www.niddk.nih.gov)
19. Novartis Pharmaceuticals, Procter & Gamble Pharmaceuticals (www.enablex.com)
20. American Urological Association (www.auanet.org)
21. The National Women's Health Information Center, U.S. Department of Health and Human Services, Office of Women's Health (www.4women.gov)
22. American Lung Association (www.lungusa.org)
23. Alzheimer's Association (www.alz.org)
24. CureResearch.com™ (www.cureresearch.com)
25. Guttmacher Institute (www.guttmacher.org)
26. National Library of Medicine, National Institutes of Health (www.nlm.nih.gov)
27. Ohio State University Medical Center, The Ohio State University (www.medicalcenter.osu.edu)
28. Urology Channel, Health Communications.com (www.urologychannel.com)
29. Health-Cares.net (www.womens-health.health-cares.net)
30. Agency for Health Care Research and Quality, U.S. Department of Health and Human Services (www.ahrq.gov)
31. National Institute of Child Health and Human Development, National Institutes of Health (www.nichd.nih.gov)
32. American Academy of Family Physicians (www.aafp.org)
33. National Institute of Mental Health, National Institutes of Health (www.nimh.nih.gov)
34. Eli Lilly and Company (www.lilly.com)
35. National Center for Health Statistics, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (www.cdc.gov/nchs)
36. Eli Lilly and Company (www.xigris.com)

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 \$43 billion in research and development in 2006.

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

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| American Academy of Allergy, Asthma and Immunology | National Association of Anorexia Nervosa and Associated Disorders |
| American Academy of Ophthalmology | National Black Nurses Association |
| American Autoimmune Related Diseases Association | National Cervical Cancer Coalition |
| American College of Allergy, Asthma and Immunology | National Council of Negro Women |
| American College of Obstetricians and Gynecologists | National Foundation for Cancer Research |
| American College of Rheumatology | National Foundation for Depressive Illness |
| American Fertility Association | National Foundation for Infectious Diseases |
| American Headache Society | National Headache Foundation |
| American Menopause Foundation | National Medical Association |
| American Nurses Association | National Multiple Sclerosis Society |
| American Skin Association | National Osteoporosis Foundation |
| Arthritis Foundation | National Psoriasis Foundation |
| Association of Community Cancer Centers | National Sarcoidosis Resource Center |
| Association of Women's Health, Obstetric, and Neonatal Nurses | National Women's Health Resource Center |
| Asthma and Allergy Foundation of America | North American Menopause Society |
| Burger King Cancer Caring Center | Office of Research on Women's Health, National Institutes of Health |
| Cancer Care | Planned Parenthood Federation of America |
| Cancer Research Institute | Prevent Blindness America |
| Chemotherapy Foundation | Scleroderma Foundation |
| Depression and Bipolar Support Alliance | Simon Foundation for Continence |
| Endometriosis Association | Sjogren's Syndrome Foundation |
| Interamerican College of Physicians & Surgeons | Society for Women's Health Research |
| Lupus Foundation of America | Society of Gynecologic Oncologists |
| Mental Health America | The V Foundation for Cancer Research |
| Multiple Sclerosis Foundation | WomenHeart: the National Coalition for Women with Heart Disease |
| NAMI: National Alliance on Mental Illness | Y-ME National Breast Cancer Organization |
| NARSAD: The Mental Health Research Association | |
| National Alliance for Hispanic Health | |

Being listed in this report in no way implies that the above-mentioned organizations endorse or recommend the use of any of the products in development contained in this publication. For further information, patients should consult their physicians or health care providers.



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