

# Heart Disease and Stroke

PRESENTED BY AMERICA'S BIOPHARMACEUTICAL RESEARCH COMPANIES

## Biopharmaceutical Research Companies Are Developing Nearly 300 Medicines for Cardiovascular Disease

**B**iopharmaceutical research companies are developing 299 new medicines for two of the leading causes of death of Americans—heart disease and stroke. The work continues the momentum of drug discovery that has helped cut deaths from these diseases by 28 percent between 1997 and 2007. All of the medicines are either in clinical trials or awaiting review by the Food and Drug Administration.

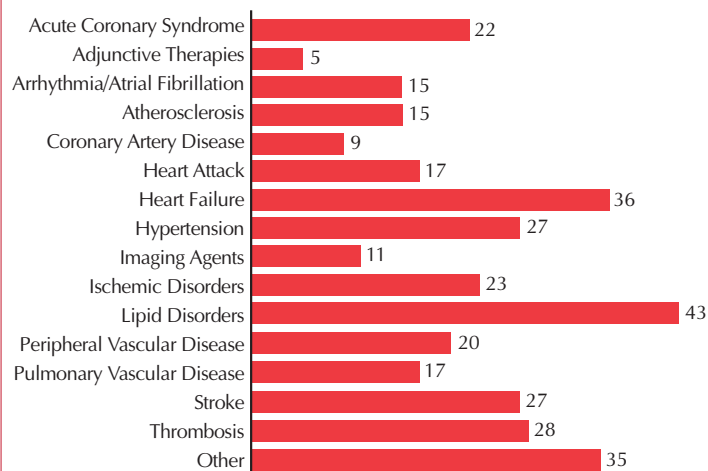
According to the National Center for Health Statistics, heart disease has topped the list of killer diseases every year but one since 1900. (The exception was 1918, when an influenza epidemic killed more than 450,000 Americans.)

Thanks in large part to new drug treatments, death rates from heart disease and stroke are falling. In 2008, stroke dropped to the fourth leading cause of death after being the third for over 50 years. According to the National Heart, Lung and Blood Institute (NHLBI), if death rates were the same as those of 30 years ago, 815,000 more Americans would die of heart disease annually and 250,000 more would die of stroke. This reduction in death rates is “one of the great triumphs of medicine in the past 50 years,” according to cardiologist Dr. Eugene Braunwald of Brigham and Women’s Hospital in Boston.

Much of the progress is due to the development of effective medicines to control both blood pressure and cholesterol, according to officials at the NHLBI. In addition, treatment of heart attacks has vastly improved. Twenty-five years ago, the treatment for heart attacks was simply bed rest. Today, doctors have medicines that can stop a heart attack in mid-stream as well as other effective treatments.

But, the war against heart disease and stroke is not yet won. According to the American Heart Association, every 39 seconds an American dies from cardiovascular disease, and more than 82 million Americans have at least one type of the disease. Many people who survive heart attacks develop heart failure, a chronic disease that affects 5.7 million Americans. The cost of these diseases to American society is more than \$503 billion a year.

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



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

The medicines in development include 43 for lipid disorders, such as high cholesterol, 36 for heart failure, 27 for high blood pressure, 17 for heart attacks, and 27 for stroke. Many of the potential medicines use cutting-edge technologies and new scientific approaches. For example:

- Human stem cells that restore cardiac function by forming new heart muscle.
- A new anticoagulant that regulates clot formation to prevent deep vein thrombosis.
- A gene therapy that uses a patient’s own cells to treat heart failure.
- A medicine that blocks the transfer of good (HDL) cholesterol to bad (LDL).

These new medicines promise to continue the already remarkable progress against heart disease and stroke and to raise the quality of life for patients suffering from these diseases.

Sincerely,  
John J. Castellani  
President and CEO  
PhRMA

# Medicines in Development for Heart Disease and Stroke

## ACUTE CORONARY SYNDROME

Product Name	Sponsor	Indication	Development Status*
<b>Brilinta™</b> ticagrelor	AstraZeneca <i>Wilmington, DE</i>	prevention of acute coronary syndrome	application submitted (800) 236-9933
CER-001	Cerenis Therapeutics <i>Ann Arbor, MI</i>	post-acute coronary syndrome	Phase I (734) 769-1110
CSL112	CSL Behring <i>King of Prussia, PA</i>	acute coronary syndrome	Phase I (610) 878-4000
E5555 (atopaxar)	Eisai <i>Woodcliff Lake, NJ</i>	acute coronary syndrome/chronic atherothrombotic disease	Phase II (888) 422-4743
<b>Effient®</b> prasugrel	Eli Lilly <i>Indianapolis, IN</i> Daiichi Sankyo <i>Parsippany, NJ</i>	acute coronary syndrome (combination therapy)	Phase III (800) 545-5979 (973) 359-2600
elinogrel	Novartis Pharmaceuticals <i>East Hanover, NJ</i> Portola Pharmaceuticals <i>South San Francisco, CA</i>	acute coronary syndrome (see also heart attack)	Phase II (888) 669-6682
losmapimod	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	acute coronary syndrome (see also atherosclerosis, lipid disorders)	Phase II (888) 825-5249
M118 (adomiparin)	Momenta Pharmaceuticals <i>Cambridge, MA</i>	acute coronary syndrome	Phase II (617) 491-9700
MDCO-216	The Medicines Company <i>Parsippany, NJ</i>	acute coronary syndrome (see also atherosclerosis)	Phase II (800) 388-1183
otamixaban (direct Xa inhibitor)	sanofi-aventis <i>Bridgewater, NJ</i>	acute coronary syndrome	Phase III (800) 633-1610
<b>Plavix®</b> clopidogrel	Bristol-Myers Squibb <i>Princeton, NJ</i> sanofi-aventis <i>Bridgewater, NJ</i>	acute coronary syndrome (high loading dose) (see also arrhythmia, other)	Phase III (212) 546-4000 (800) 633-1610
<b>Pradaxa®</b> dabigatran etexilate	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	acute coronary syndrome (prevention of cardiovascular events) (see also thrombosis)	Phase II (203) 798-9988
REG1	Regado Biosciences <i>Basking Ridge, NJ</i>	acute coronary syndrome	Phase II (908) 580-2100
rivaroxaban	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	acute coronary syndrome (Fast Track) (see also stroke, thrombosis)	Phase III (888) 842-2937 (800) 817-5286

\* For more information about a specific medicine in this report, please use contact information provided.

## ACUTE CORONARY SYNDROME

Product Name	Sponsor	Indication	Development Status
RVX-208	Resverlogix <i>Calgary, Canada</i>	acute coronary syndrome (see also atherosclerosis)	Phase II (403) 254-9252
TAK-442 (letaxaban)	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	acute coronary syndrome (see also thrombosis)	Phase II (877) 582-5332
<b>Valturna</b> <sup>®</sup> aliskiren/valsartan	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	acute coronary syndrome	Phase II (888) 669-6682
vaespladib	Anthera Pharmaceuticals <i>San Mateo, CA</i>	acute coronary syndrome (see also atherosclerosis)	Phase III (510) 277-0356
VIA-2291	VIA Pharmaceuticals <i>San Francisco, CA</i>	acute coronary syndrome (see also atherosclerosis)	Phase II (415) 283-2200
vorapaxar	Merck <i>Whitehouse Station, NJ</i>	acute coronary syndrome (Fast Track) (see also thrombosis)	Phase III (800) 672-6372
VT-111	Viron Therapeutics <i>London, Canada</i>	acute coronary syndrome	Phase II (519) 858-5109
<b>Vytorin</b> <sup>™</sup> ezetimibe/ simvastatin	Merck <i>Whitehouse Station, NJ</i>	acute coronary syndrome	Phase III (800) 672-6372

## ADJUNCTIVE THERAPIES; REVASCLARIZATION

Product Name	Sponsor	Indication	Development Status
AP 214	Action Pharma <i>Arhus, Denmark</i>	prevention of kidney disorders in cardiac surgery	Phase II <a href="http://www.actionpharma.com">www.actionpharma.com</a>
CCX140	ChemoCentryx <i>Mountain View, CA</i>	treatment of vascular restinosis following angioplasty or stenting	Phase I completed (650) 210-2900
CU-2010	The Medicines Company <i>Parsippany, NJ</i>	prevention of blood loss during cardiac surgery	Phase I (800) 388-1183
rFXIII	Novo Nordisk <i>Princeton, NJ</i>	post-operative hemorrhage in cardiac surgery	Phase II (800) 727-6500
<b>Trinam</b> <sup>®</sup> taberminogene vadenovec <b>(Orphan Drug)</b>	Ark Therapeutics <i>London, United Kingdom</i>	prevention of vascular restinosis following vascular graft surgery (Fast Track)	Phase II/III <a href="http://www.arktherapeutics.com">www.arktherapeutics.com</a>

## ARRHYTHMIA, ATRIAL FIBRILLATION

Product Name	Sponsor	Indication	Development Status
ATI-2042 (budiardone)	ARYx Therapeutics <i>Fremont, CA</i>	atrial fibrillation	Phase II completed (510) 585-2200

## ARRHYTHMIA, ATRIAL FIBRILLATION

Product Name	Sponsor	Indication	Development Status
ATPace™ adenosine triphosphate injection	Cordex Pharma <i>La Jolla, CA</i>	bradycardia	Phase II (858) 551-5700
		paroxysmal supraventricular tachycardia (PSVT)	Phase II (858) 551-5700
azimilide	Blue Ash Therapeutics <i>Cincinnati, OH</i>	ventricular arrhythmia	Phase III (513) 554-0696
BMS-394136 (potassium channel blocker)	Bristol-Myers Squibb <i>Princeton, NJ</i>	arrhythmia	Phase I (212) 546-4000
BMS-914392	Bristol-Myers Squibb <i>Princeton, NJ</i>	atrial fibrillation	Phase I (212) 546-4000
capadenoson	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	atrial fibrillation	Phase II completed (888) 842-2937
celivarone	sanofi-aventis <i>Bridgewater, NJ</i>	ventricular arrhythmia	Phase II (800) 633-1610
danegaptide	Pfizer <i>New York, NY</i> Zealand Pharma <i>Copenhagen, Denmark</i>	atrial fibrillation	Phase I completed (860) 732-5156
K201 (JTV-519)	Sequel Pharmaceuticals <i>San Diego, CA</i>	atrial fibrillation	Phase II (858) 509-0455
Kynapid™ vernakalant (intravenous)	Astellas Pharma <i>Deerfield, IL</i> Cardiome Pharma <i>Vancouver, Canada</i>	atrial fibrillation	application submitted (800) 727-7003 (800) 330-9928
Lipitor® atorvastatin	Pfizer <i>New York, NY</i>	prevention of atrial fibrillation	in clinical trials (860) 732-5156
Lovaza® omega-3 acid ethyl esters	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	atrial fibrillation (see also lipid disorders)	Phase III completed (888) 825-5249
NTC-801	Bristol-Myers Squibb <i>Princeton, NJ</i> Nissan Chemical <i>Tokyo, Japan</i> Teijin Pharma <i>Tokyo, Japan</i>	atrial fibrillation, atrial flutter	Phase II (212) 546-4000
Plavix® clopidogrel	Bristol-Myers Squibb <i>Princeton, NJ</i> sanofi-aventis <i>Bridgewater, NJ</i>	atrial fibrillation (see also acute coronary syndrome, other)	application submitted (212) 546-4000 (800) 633-1610
vernakalant (oral)	Cardiome Pharma <i>Vancouver, Canada</i> Merck <i>Whitehouse Station, NJ</i>	atrial fibrillation	Phase II (800) 330-9928 (800) 672-6372

## ATHEROSCLEROSIS

Product Name	Sponsor	Indication	Development Status
anacetrapib (MK-0859)	Merck <i>Whitehouse Station, NJ</i>	atherosclerosis (see also lipid disorders)	Phase III (800) 672-6372
BMS-582949 (kinase inhibitor)	Bristol-Myers Squibb <i>Princeton, NJ</i>	atherosclerosis	Phase II (212) 546-4000
BMS-779788 (liver XR agonist)	Bristol-Myers Squibb <i>Princeton, NJ</i> Exelixis <i>San Francisco, CA</i>	atherosclerosis	Phase I completed (212) 546-4000
darapladib (Lp-PLA2 inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	atherosclerosis	Phase III (888) 825-5249
GSK568859 (lipoprotein- associated phospholipase A2 [Lp-PLA2] inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	atherosclerosis	Phase I (888) 825-5249
K-604	Kowa Pharmaceuticals America <i>Montgomery, AL</i>	atherosclerosis	Phase I (334) 288-1288
losmapimod	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	atherosclerosis (see also acute coronary syndrome, lipid disorders)	Phase I (888) 825-5249
MDCO-216	The Medicines Company <i>Parsippany, NJ</i>	atherosclerosis (see also acute coronary syndrome)	Phase II (800) 388-1183
PSI-697	Pfizer <i>New York, NY</i>	atherosclerosis (see also thrombosis)	Phase I (860) 732-5156
RG1658 (dalcetrapib)	Roche <i>Nutley, NJ</i>	atherosclerosis (cardiovascular risk reduction)	Phase III (973) 235-5000
RG7418 (BI204)	BiInvent <i>Lund, Sweden</i> Genentech <i>South San Francisco, CA</i>	atherosclerosis	Phase I (800) 626-3553
rilapladib (Lp-PLA2 inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Human Genome Sciences <i>Rockville, MD</i>	atherosclerosis	Phase II completed (888) 825-5249 (301) 309-8504
RVX-208	Resverlogix <i>Calgary, Canada</i>	atherosclerosis (see also acute coronary syndrome)	Phase II (403) 254-9252
vaespladib	Anthera Pharmaceuticals <i>San Mateo, CA</i>	atherosclerosis (see also acute coronary syndrome)	Phase II completed (510) 277-0356
VIA-2291	VIA Pharmaceuticals <i>San Francisco, CA</i>	atherosclerosis (see also acute coronary syndrome)	Phase II (415) 383-2200

## CORONARY ARTERY DISEASE

Product Name	Sponsor	Indication	Development Status
coronary artery disease gene therapy	BioCardia <i>South San Francisco, CA</i>	coronary artery disease	Phase II (650) 624-0900
<b>Coroxane™</b> albumin-bound paclitaxel (intra-arterial)	Abraxis BioScience <i>Los Angeles, CA</i>	coronary artery restenosis (see also peripheral vascular disease)	Phase II (310) 437-7700
ivabradine	Servier <i>Cedex, France</i>	coronary artery disease with left ventricular dysfunction	Phase III www.servier.com
K-134	Kowa Pharmaceuticals America <i>Montgomery, AL</i>	arteriosclerosis obliterans	Phase II (334) 288-1288
LT-1951	Lumen Therapeutics <i>Mountain View, CA</i>	coronary artery restenosis	Phase I/II (650) 641-0084
myolimus	Elixir Medical <i>Sunnyvale, CA</i>	coronary artery restenosis	in clinical trials (408) 636-2000
novolimus	Elixir Medical <i>Sunnyvale, CA</i>	prevention of coronary artery restenosis	Phase II/III (408) 636-2000
<b>Resten-MP™</b>	Cook Pharmica <i>Bloomington, IN</i>	coronary artery restenosis	Phase I (877) 312-2665
<b>Resten-NG®</b>	Cook Pharmica <i>Bloomington, IN</i>	coronary artery restenosis	Phase II (877) 312-2665

## HEART ATTACK (MYOCARDIAL INFARCTION)

Product Name	Sponsor	Indication	Development Status
adipose stem cell therapy	Cytori Therapeutics <i>San Diego, CA</i>	myocardial infarction (see also ischemic disorders)	Phase I (858) 458-0900
AMR-001 (stem cell therapy)	Amorcyte <i>Hackensack, NJ</i> Progenitor Cell Therapy <i>Hackensack, NJ</i>	myocardial infarction	Phase I (201) 883-5300 (201) 883-5303
APN01	Apeiron Biologics <i>Vienna, Austria</i> GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	myocardial infarction (see also heart failure, hypertension)	Phase I (888) 825-5249
<b>Bendavia™</b>	Stealth Peptides <i>Newton Centre, MA</i>	acute myocardial infarction	Phase II (617) 244-2800
BVI-007	BioVascular <i>San Diego, CA</i>	myocardial infarction (see also stroke)	Phase I (858) 455-5000
carperitide	Asubio Pharmaceuticals <i>Rochelle Park, NJ</i>	acute myocardial infarction	Phase III (201) 368-5020
elinogrel	Novartis Pharmaceuticals <i>East Hanover, NJ</i> Portola Pharmaceuticals <i>South San Francisco, CA</i>	myocardial infarction (see also acute coronary syndrome)	Phase II (888) 669-6682

## HEART ATTACK (MYOCARDIAL INFARCTION)

Product Name	Sponsor	Indication	Development Status
<b>MultiStem®</b> stem cell therapy	Athersys <i>Cleveland, OH</i>	myocardial infarction (see also stroke)	Phase II (216) 431-9900
Neu2000	AmKor Pharma <i>Seattle, WA</i>	myocardial infarction (see also stroke)	Phase I www.amkorpharma.com
NX-CP-105 (stem cell therapy)	Neuronyx <i>Malvern, PA</i>	myocardial infarction	Phase I (610) 240-4150
PL2100 (aspirin/ phosphatidyl- choline)	PLx Pharma <i>Houston, TX</i>	myocardial infarction (see also stroke)	Phase I/II (713) 842-1249
<b>Prochymal™</b> mesenchymal stem cell therapy (human)	Osiris Therapeutics <i>Baltimore, MD</i>	repair of heart tissue following myocardial infarction	Phase II (410) 522-5005
<b>Revascor™</b> mesenchymal stem cell therapy	Angioblast Systems <i>New York, NY</i> Mesoblast <i>Melbourne, Australia</i>	myocardial infarction (see also heart failure)	Phase II (212) 880-2060
<b>Tekturna®</b> aliskiren	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	myocardial infarction (see also heart failure, hypertension)	Phase III (888) 669-6682
TG-100115	sanofi-aventis <i>Bridgewater, NJ</i>	myocardial infarction (Fast Track)	Phase I/II (800) 633-1610
thymosin beta-4	ReGeneRx Biopharmaceuticals <i>Bethesda, MD</i>	myocardial infarction	Phase I (301) 280-1992
VMD-30283	VM Discovery <i>Fremont, CA</i>	myocardial infarction	Phase I/II (510) 661-6770

## HEART FAILURE (CONGESTIVE HEART FAILURE)

Product Name	Sponsor	Indication	Development Status
AMG 423 (omecamtiv mecarbil)	Amgen <i>Thousand Oaks, CA</i> CytoKinetics <i>South San Francisco, CA</i>	heart failure (see also other)	Phase II (805) 447-1000 (650) 624-3000
<b>Anginera™</b> epicardial angiogenesis patch	Theregen <i>San Francisco, CA</i>	heart failure (see also ischemic disorders)	Phase I (415) 439-8320
APN01	Apeiron Biologics <i>Vienna, Austria</i> GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	heart failure (see also heart attack, hypertension)	Phase I (888) 825-5249
BAY 60-4552	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	heart failure	Phase II (888) 842-2937

## HEART FAILURE (CONGESTIVE HEART FAILURE)

Product Name	Sponsor	Indication	Development Status
BB3	Angion Therapeutics <i>Manhasset, NY</i>	prevention of congestive heart failure	Phase II (516) 869-6400
<b>Bidil XR™</b> hydralazine hydrochloride/ isosorbide dinitrate (extended-release)	NitroMed <i>Charlotte, NC</i>	heart failure	Phase I (704) 941-2020
BR-4628	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	congestive heart failure	Phase I (888) 842-2937
<b>Bystolic®</b> nebivolol	Forest Laboratories <i>New York, NY</i>	congestive heart failure	application submitted (800) 678-1605
<b>Cardeva™</b> B-type natriuretic peptide	Teva Pharmaceuticals USA <i>North Wales, PA</i>	chronic heart failure	Phase I/II (215) 591-3000
CD-NP	Niles Therapeutics <i>San Francisco, CA</i>	heart failure	Phase II (415) 875-7880
cinaciguat (BAY 58-2667)	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	acute decompensated heart failure	Phase II (888) 842-2937
CXL-1020	Cardioxyl Pharmaceuticals <i>Chapel Hill, NC</i>	chronic heart failure	Phase II (919) 869-8585
daglutril	Abbott Laboratories <i>Abbott Park, IL</i>	congestive heart failure (see also hypertension)	Phase II (847) 937-6100
<b>Gencaro™</b> bucindolol	ARCA biopharma <i>Broomfield, CO</i>	genotype-defined heart failure (Fast Track)	application submitted (720) 940-2200
GGF (glial growth factor)	Acorda Therapeutics <i>Hawthorne, NY</i>	congestive heart failure	Phase I (914) 347-4300
icodextrin solution	Baxter Healthcare <i>Deerfield, IL</i>	congestive heart failure	Phase II (800) 422-9837
IK-5001	Ikaria <i>Clinton, NJ</i>	cardiac remodeling and subsequent congestive heart failure following acute myocardial infarction	Phase II (908) 238-6600
<b>INOmax®</b> nitric oxide inhalation	Ikaria <i>Clinton, NJ</i>	congestive heart failure (see also ischemic disorders)	Phase II completed (908) 238-6600
<b>Inspira®</b> eplerenone	Pfizer <i>New York, NY</i>	mild to moderate chronic heart failure	Phase III (860) 732-5156
JNJ-39588146	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	heart failure	Phase II (800) 817-5286
LCI699	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	heart failure (see also hypertension)	Phase II (888) 669-6682
LCZ696	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	heart failure (see also hypertension)	Phase III (888) 669-6682

## HEART FAILURE (CONGESTIVE HEART FAILURE)

Product Name	Sponsor	Indication	Development Status
<b>Mydicar™</b> AAV1/SERCA2a gene therapy	Celladon <i>La Jolla, CA</i> Targeted Genetics <i>Seattle, WA</i>	advanced heart failure (class III/IV)	Phase I/II (858) 366-4288 (206) 623-7612
myoblast cell transplantation therapy	Advanced Cell Technology <i>Santa Monica, CA</i>	congestive heart failure	Phase I (310) 576-0611
<b>MyoCell®</b> cell-based heart damage therapy (tissue regeneration)	Bioheart <i>Sunrise, FL</i>	congestive heart failure	Phase II/III (954) 835-1500
PL-3994	Palatin Technologies <i>Cranbury, NJ</i>	congestive heart failure (see also hypertension)	Phase II (609) 495-2200
recombinant relaxin (RLX030)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	acute heart failure (Fast Track)	Phase III (888) 669-6682
<b>Revascor™</b> mesenchymal stem cell therapy	Angioblast Systems <i>New York, NY</i> Mesoblast <i>Melbourne, Australia</i>	prevention of heart failure (see also heart attack)	Phase II (212) 880-2060
RWJ-676070	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	congestive heart failure (see also other)	Phase I (800) 817-5286
SDF-1 (JVS-100)	Juventas Therapeutics <i>Cleveland, OH</i>	heart failure	Phase I (216) 445-0830
SLV320	Abbott Laboratories <i>Abbott Park, IL</i>	acute heart failure, congestive heart failure	Phase II (847) 937-6100
T3 (lithyronine modified release)	Archimedes Pharma <i>Nottingham, United Kingdom</i> T3 Therapeutics <i>Manhasset, NY</i>	congestive heart failure	Phase I (516) 562-1040
<b>Tekturna®</b> aliskiren	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	acute heart failure in the elderly, congestive heart failure (see also heart attack, hypertension)	Phase III (888) 669-6682
TRV120027	Trevena <i>King of Prussia, PA</i>	acute heart failure	Phase I (610) 354-8840
ularitide	EKR Therapeutics <i>Bedminster, NJ</i>	acute decompensated heart failure	Phase I (877) 435-2524
urocortin 2	Neurocrine Biosciences <i>San Diego, CA</i>	congestive heart failure	Phase II (858) 617-7600

## HYPERTENSION (HIGH BLOOD PRESSURE)

Product Name	Sponsor	Indication	Development Status
ACT-280778	Actelion Pharmaceuticals US <i>South San Francisco, CA</i>	essential hypertension	Phase II (650) 624-6900
ADX-415	Shionogi <i>Florham Park, NJ</i>	hypertension	Phase II (973) 966-6900
amlodipine/ irbesartan fixed-dose combination	sanofi-aventis <i>Bridgewater, NJ</i>	hypertension	Phase III completed (800) 633-1610
angiotensin inhibitor therapeutic vaccine	BTG International <i>West Conshohocken, PA</i>	hypertension	Phase I (610) 278-1660
APN01	Apeiron Biologics <i>Vienna, Austria</i> GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	hypertension (see also heart attack, heart failure)	Phase I (888) 825-5249
AR9281	Arête Therapeutics <i>Hayward, CA</i>	hypertension	Phase II (510) 785-7060
BAY 98-7106 (candesartan cilexetil/nifedipine)	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	hypertension	Phase I (888) 842-2937
daglutril	Abbott Laboratories <i>Abbott Park, IL</i>	hypertension (see also heart failure)	Phase II (847) 937-6100
HTI-101 (amiloride/ spironolactone)	Hemodynamic Therapeutics <i>Durham, NC</i>	obesity-related resistant hypertension	Phase II (919) 361-2286
INT0001/2004	DAVA Pharmaceuticals <i>Fort Lee, NJ</i> IntelGenx <i>St-Laurent, Canada</i>	hypertension	Phase I (514) 331-7440
irbesartan/ trichlormethiazide fixed-dose combination	Shionogi <i>Florham Park, NJ</i>	hypertension	Phase III (973) 966-6900
<b>Jenloga-XR®</b> clonidine controlled-release (once-daily)	Shionogi <i>Florham Park, NJ</i>	hypertension	Phase III completed (973) 966-6900
LCI699	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	hypertension (see also heart failure)	Phase II (888) 669-6682
LCZ696	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	hypertension (see also heart failure)	Phase II (888) 669-6682
lercanidipine MR (modified-release)	Forest Laboratories <i>New York, NY</i>	hypertension	Phase II (800) 678-1605
<b>Micardis®</b> telmisartan	Boehringer-Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	hypertension in adolescents and children	Phase II completed (800) 243-0127

## HYPERTENSION (HIGH BLOOD PRESSURE)

Product Name	Sponsor	Indication	Development Status
MK-3614	Merck <i>Whitehouse Station, NJ</i>	hypertension	Phase I (800) 672-6372
MK-5478	Merck <i>Whitehouse Station, NJ</i>	hypertension	Phase I (800) 672-6372
MK-8266	Merck <i>Whitehouse Station, NJ</i>	essential hypertension	Phase I (800) 672-6372
PL-3994	Palatin Technologies <i>Cranbury, NJ</i>	hypertension (see also heart failure)	Phase II (609) 495-2200
PS433540	Ligand Pharmaceuticals <i>La Jolla, CA</i>	hypertension	Phase II (858) 550-7500
sapropterin	BioMarin Pharmaceutical <i>Novato, CA</i>	hypertension (see also peripheral vascular disorders)	Phase II (415) 560-6700
SLx-2101	Surface Logix <i>Brighton, MA</i>	hypertension (see also other)	Phase II (617) 746-8500
TAK-491 (azilsartan medoxomil)	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	hypertension	application submitted (877) 582-5332
		hypertension in adolescents, children and infants	Phase I (877) 582-5332
TAK-491CLD (azilsartan medoxomil/ chlortalidone)	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	hypertension	Phase III (877) 582-5332
<b>Tektura</b> <sup>®</sup> aliskiren	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	hypertension in adolescents and children (see also heart attack, heart failure)	Phase III (888) 669-6682
VTP-27999	Vitae Pharmaceuticals <i>Fort Washington, PA</i>	hypertension	Phase I (215) 461-2000

## IMAGING AGENTS

Product Name	Sponsor	Indication	Development Status
18F-flurpiridaz (BMS-747158)	Lantheus Medical Imaging <i>N. Billerica, MA</i>	diagnosis of coronary disorders	Phase II (800) 362-2668
<b>AdreView</b> <sup>™</sup> iobenguane I 123 injection	GE Healthcare <i>Waukesha, WI</i>	diagnosis of heart failure	Phase III completed (800) 345-2700
cardiac PET imaging agent	FluoroPharma <i>Boston, MA</i>	diagnosis of coronary artery disease	Phase I (617) 482-2333
<b>CorVue</b> <sup>™</sup> binodenoson	King Pharmaceuticals <i>Bristol, TN</i>	diagnosis of cardiovascular disorders	application submitted (800) 776-3637
<b>Feraheme</b> <sup>™</sup> ferumoxytol	AMAG Pharmaceuticals <i>Lexington, MA</i>	diagnosis of peripheral arterial disorders (Fast Track)	Phase II (617) 498-3300

## IMAGING AGENTS

Product Name	Sponsor	Indication	Development Status
<b>Gadovist</b> <sup>®</sup> gadobutrol	Bayer HealthCare Pharmaceuticals Wayne, NJ	diagnosis of vascular disorders	application submitted (888) 842-2937
<b>Imagify</b> <sup>™</sup> perflubutane	Acusphere Watertown, MA	detection of coronary artery disease	application submitted (617) 648-8800
LMI1195	Lantheus Medical Imaging N. Billerica, MA	diagnosis of heart failure	Phase I (800) 362-2668
myocardial perfusion imaging agent	FluoroPharma Boston, MA	diagnosis of coronary disorders	Phase I (617) 482-2333
<b>Stedivaze</b> <sup>™</sup> apadenoson	PGx Health New Haven, CT	diagnosis of coronary disorders	Phase III (877) 274-9432
<b>Zemiva</b> <sup>™</sup> iodofilic acid I-123	Molecular Insight Pharmaceuticals Cambridge, MA	diagnosis of myocardial ischemia	Phase II completed (617) 492-5554

## ISCHEMIC DISORDERS

Product Name	Sponsor	Indication	Development Status
ACY001 (stem cell therapy)	Arteriocyte Cleveland, OH	chronic ischemia	Phase I completed (216) 456-9640
adipose stem cell therapy	Cytori Therapeutics San Diego, CA	myocardial ischemia (see also heart attack)	Phase I (858) 458-0900
adult stem cell therapy	Baxter Healthcare Deerfield, IL	chronic myocardial ischemia	Phase II completed (800) 422-9837
		critical limb ischemia	Phase I/II completed (800) 422-9837
ALD-201 (autologous stem cell therapy)	Aldagen Durham, NC	ischemic heart failure	Phase I completed (919) 484-2571
ALD-301 (autologous stem cell therapy)	Aldagen Durham, NC	critical limb ischemia	Phase I/II (919) 484-2571
ALO 212	Arteriocyte Cleveland, OH	critical limb ischemia	Phase I (216) 456-9640
<b>Anginera</b> <sup>™</sup> epicardial angiogenesis patch	Theregen San Francisco, CA	ischemic heart disease (see also heart failure)	Phase I (415) 439-8320
autologous cell therapy	BioCardia San Carlos, CA	ischemic heart disease	Phase I (800) 624-1179
bepmeringene perplasmid	AnGes Gaithersburg, MD Daiichi Sankyo Parsippany, NJ	ischemic heart disease (see also peripheral vascular disease)	Phase I (973) 359-2600

## ISCHEMIC DISORDERS

Product Name	Sponsor	Indication	Development Status
cangrelor	The Medicines Company <i>Parsippany, NJ</i>	prevention of ischemic heart disorders (see also thrombosis)	Phase III (800) 388-1183
CMX-2043	Ischemix <i>Maynard, MA</i>	prevention of myocardial reperfusion injury	Phase II (978) 897-5139
diannexin	Altavita Pharmaceuticals <i>Mountain View, CA</i> Astellas Pharma US <i>Deerfield, IL</i>	myocardial reperfusion injury	Phase II completed (800) 727-7003
<b>Generx™</b> alferminogene tadenovec	Cardium Therapeutics <i>San Diego, CA</i>	myocardial ischemia (Fast Track)	Phase III (858) 436-1000
GP-531	PeriCor Therapeutics <i>New York, NY</i>	myocardial ischemia	Phase II (212) 601-2725
<b>Hemospan™</b> human hemoglobin	Sangart <i>San Diego, CA</i>	ischemia	Phase II completed (858) 450-2400
<b>INOmax®</b> nitric oxide inhalation	Ikaria <i>Clinton, NJ</i>	prevention of myocardial reperfusion injury (see also heart failure)	Phase II/III (908) 238-6600
KAI-9803/ BMS-875944 (PKC-Delta inhibitor)	Bristol-Myers Squibb <i>Princeton, NJ</i> KAI Pharmaceuticals <i>South San Francisco, CA</i>	prevention of reperfusion injury following acute myocardial infarction (Fast Track)	Phase II (212) 546-4000 (650) 244-1100
<b>Ranexa®</b> ranolazine extended-release	Gilead Sciences <i>Foster City, CA</i>	myocardial ischemia	Phase II completed (800) 445-3235
<b>Remodulin®</b> treprostnil	United Therapeutics <i>Silver Spring, MD</i>	critical limb ischemia (see also pulmonary vascular disease)	Phase II (301) 608-9292
<b>Temusi®</b> riferminogene pecaplasmid	sanofi-aventis <i>Bridgewater, NJ</i>	critical limb ischemia	Phase III (800) 633-1610
tissue repair stem cell therapy	Aastrom Biosciences <i>Ann Arbor, MI</i>	peripheral ischemia (see also other)	Phase II (734) 930-5555
VM-202 (modified hepatocyte growth factor gene therapy)	ViroMed <i>Seoul, Korea</i>	myocardial ischemia (see also peripheral vascular disease)	Phase I www.viomed.co.kr
YSPSL (recombinant P-selection glycoprotein ligand-1 fusion protein)	Y's Therapeutics <i>San Bruno, CA</i>	prevention of myocardial reperfusion injury associated with liver transplantation	Phase II (650) 777-7000

## LIPID DISORDERS

Product Name	Sponsor	Indication	Development Status
1-MNA	Pharmena North America <i>Boston, MA</i>	hyperlipidemia	Phase II/III www.pharmena.com
AEGR-733 (lomitapide) <b>(Orphan Drug)</b>	Aegerion Pharmaceuticals <i>Bridgewater, NJ</i>	hyperlipoproteinemia type II ----- hypercholesterolemia	Phase III (908) 707-2100  Phase II (908) 707-2100
AMG 145	Amgen <i>Thousand Oaks, CA</i>	hypercholesterolemia ----- hyperlipidemia	Phase I (805) 447-1000  Phase I (805) 447-1000
AMR101	Amarin <i>Mystic, CT</i>	hypertriglyceridemia	Phase III (866) 960-7367
AMT-011 (alipogene tiparvovec) <b>(Orphan Drug)</b>	Amsterdam Molecular Therapeutics <i>Amsterdam, The Netherlands</i>	hyperlipoproteinemia type I (lipoprotein lipase deficiency)	Phase I www.amybiopharma.com
anacetrapib (MK-0859)	Merck <i>Whitehouse Station, NJ</i>	hypercholesterolemia, mixed dyslipidemia (see also atherosclerosis)	Phase II (800) 672-6372
atorvastatin/ ezetimibe	Merck <i>Whitehouse Station, NJ</i>	hypercholesterolemia	Phase III (800) 672-6372
BMS-180431 (HmG-CoA reductase inhibitor)	Bristol-Myers Squibb <i>Princeton, NJ</i>	hyperlipidemia	Phase II (212) 546-4000
BMS-770767 (11b-HSD1 inhibitor)	Bristol-Myers Squibb <i>Princeton, NJ</i>	hypercholesterolemia	Phase II (212) 546-4000
BMS-823778	Bristol-Myers Squibb <i>Princeton, NJ</i>	hypercholesterolemia	Phase II (212) 546-4000
CER-002	Cerenis Therapeutics <i>Ann Arbor, MI</i>	dyslipidemia with low HDL	Phase I (734) 769-1110
CER-627	Cerenis Therapeutics <i>Ann Arbor, MI</i>	dyslipidemia with low HDL	Phase I (734) 769-1110
DCCR (diazoxide choline controlled-release)	Essentials <i>San Diego, CA</i>	dyslipidemia	Phase II (858) 964-5028
<b>Espanova™</b> eicosapentaenoic acid/docosa- hexaenoic acid	Omthera Pharmaceuticals <i>Bedminster, NJ</i>	hypertriglyceridemia	Phase I/II (908) 741-4399
ETC-1002	Esperion Therapeutics <i>Plymouth, MI</i>	dyslipidemia	Phase I www.esperion.com
fenofibrate/ pravastatin	Shionogi <i>Florham Park, NJ</i>	hyperlipidemia	application submitted (973) 966-6900

## LIPID DISORDERS

Product Name	Sponsor	Indication	Development Status
fenofibrate/ simvastatin	Abbott Laboratories <i>Abbott Park, IL</i>	hyperlipidemia	Phase III (847) 937-6100
GS 9667	Gilead Sciences <i>Foster City, CA</i>	hypertriglyceridemia	Phase I (800) 445-3235
GSK256073 (G protein- coupled receptor agonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	dyslipidemia	Phase II (888) 825-5249
GSK1292263 (bombesin receptor agonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	hyperlipidemia	Phase II (888) 825-5249
HPP-593	High Point Pharmaceuticals <i>High Point, NC</i>	dyslipidemia	Phase I (336) 841-0300
ISIS-APOCIII Rx	Isis Pharmaceuticals <i>Carlsbad, CA</i>	hypertriglyceridemia	Phase I (760) 931-9200
laropiprant/niacin/ simvastatin combination	Merck <i>Whitehouse Station, NJ</i>	hyperlipidemia	Phase III (800) 672-6372
LCQ908	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	hyperlipoproteinemia type I, hyperlipoproteinemia type V	Phase I/II (888) 669-6682
losmapimod	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	dyslipidemia (see also acute coronary syndrome, atherosclerosis)	Phase II (888) 825-5249
<b>Lovaza</b> <sup>®</sup> mega-3-acid ethyl esters	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	hypertriglyceridemia (combination therapy) (see also arrhythmia)	Phase III (888) 825-5249
LY2484595	Eli Lilly <i>Indianapolis, IN</i>	hypercholesterolemia, low HDL cholesterol	Phase II (800) 545-5979
MB-07811 (thyroid receptor beta agonist)	Ligand Pharmaceuticals <i>La Jolla, CA</i>	hyperlipidemia	Phase I (858) 550-7500
MBX-8025	Metabolex <i>Hayward, CA</i>	dyslipidemia	Phase II completed (510) 293-8800
MD-0727 (cholesterol absorption inhibitor)	Ironwood Pharmaceuticals <i>Cambridge, MA</i>	hypercholesterolemia	Phase II (617) 621-7722
mipomersen <b>(Orphan Drug)</b>	Genzyme <i>Cambridge, MA</i> Isis Pharmaceuticals <i>Carlsbad, CA</i>	hypercholesterolemia, hyperlipoproteinemia type IIa	Phase III (617) 252-7500 (760) 931-9200
PF-04950615	Pfizer <i>New York, NY</i>	hyperlipidemia	Phase I (860) 732-5156
RBx10558	PPD <i>Wilmington, DE</i>	hyperlipidemia	Phase I (910) 251-0081
RG7232 (ABCA1 inducer)	Roche <i>Nutley, NJ</i>	dyslipidemia	Phase I (973) 235-5000

## LIPID DISORDERS

Product Name	Sponsor	Indication	Development Status
SAR236553 (REGN727)	Regeneron Pharmaceuticals <i>Tarrytown, NY</i> sanofi-aventis <i>Bridgewater, NJ</i>	hypercholesterolemia	Phase I (914) 345-7400 (800) 633-1610
SCH-900271	Merck <i>Whitehouse Station, NJ</i>	hyperlipidemia	Phase II completed (800) 672-6372
SLx-4090	Surface Logix <i>Brighton, MA</i>	dyslipidemia	Phase II (617) 746-8500
sobetirome	QuatRx Pharmaceuticals <i>Ann Arbor, MI</i>	dyslipidemia	Phase I (734) 913-9900
sodelglitazar	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	hyperlipidemia	Phase II (888) 825-5249
TKM-ApoB	Tekmira Pharmaceuticals <i>British Columbia, Canada</i>	hypercholesterolemia	Phase I (604) 419-3200
<b>Tredaptive™</b> laropiprant/niacin	Merck <i>Whitehouse Station, NJ</i>	hypercholesterolemia	Phase III (800) 672-6372
<b>TriLipix®</b> choline fenofibrate	Abbott Laboratories <i>Abbott Park, IL</i>	hyperlipidemia (combination therapy)	Phase III (847) 937-6100
turofexorate isopropyl	Pfizer <i>New York, NY</i>	hyperlipidemia	Phase I (860) 732-5156

## PERIPHERAL VASCULAR DISEASE

Product Name	Sponsor	Indication	Development Status
ANGX-1039	Angiogenix <i>Burlingame, CA</i>	intermittent claudication	Phase I (650) 579-6685
bepermingene perplasmid	AnGes <i>Gaithersburg, MD</i> Daiichi Sankyo <i>Parsippany, NJ</i>	peripheral arterial disease (Fast Track) (see also ischemic disorders)	Phase II (973) 359-2600
<b>Coroxane™</b> albumin-bound paclitaxel (intra-arterial)	Abraxis BioScience <i>Los Angeles, CA</i>	peripheral arterial disease, prevention of vascular restinosis (see also coronary artery disease)	Phase II (310) 437-7700
defibrotide <b>(Orphan Drug)</b>	Gentium <i>Villa Guardia, Italy</i> Sigma-Tau Pharmaceuticals <i>Gaithersburg, MD</i>	venous-occlusive disorders (Fast Track)	Phase III (800) 447-0169
FGF-1 (fibroblast growth factor 1)	CardioVascular BioTherapeutics <i>Las Vegas, NV</i>	peripheral arterial disorders (see also other)	Phase I (702) 248-1174
HIF-1 alpha gene therapy	Genzyme <i>Cambridge, MA</i>	occlusive arterial disease	Phase II (617) 252-7500
INDI-702	Indigo Pharmaceuticals <i>New York, NY</i>	intermittent claudication	Phase III (212) 554-4283

## PERIPHERAL VASCULAR DISEASE

Product Name	Sponsor	Indication	Development Status
<b>Liprostin™</b> alprostadil	Liprostin <i>Montgomery, TX</i>	peripheral arterial disease	Phase II (936) 582-5920
<b>MultiGeneAngio</b> cell therapy	MultiGene Vascular Systems <i>Nesher, Israel</i>	peripheral arterial disorders	Phase I/II www.mgvs.co.il
paclitaxel (intra-arterial)	Angiotech Pharmaceuticals <i>Vancouver, Canada</i>	vascular restenosis	Phase III (604) 221-7676
PLX-PAD	Pluristem Therapeutics <i>Haifa, Israel</i>	critical limb ischemia	Phase I www.pluristem.com
PRT-201 <b>(Orphan Drug)</b>	Proteon Therapeutics <i>Waltham, MA</i>	vascular access for hemodialysis	Phase I/II (781) 890-0102
PVS-10200	Pervasis Therapeutics <i>Cambridge, MA</i>	peripheral arterial disorders	Phase I/II (617) 621-3407
RG1512 (P-selectin huMAb)	Roche <i>Nutley, NJ</i>	peripheral vascular disease	Phase I (973) 235-5000
RO-4905417	Roche <i>Nutley, NJ</i>	peripheral arterial disease	Phase I (973) 235-5000
sapropterin	BioMarin Pharmaceutical <i>Novato, CA</i>	peripheral arterial disease (see also hypertension)	Phase II (415) 560-6700
SPI-017	Sucampo Pharmaceuticals <i>Bethesda, MD</i>	peripheral arterial disorders	Phase I (301) 961-3400
TAL-0500018 (human plasma- derived fibrinolysin) <b>(Orphan Drug)</b>	Talecris Therapeutics <i>Rsch. Triangle Park, NC</i>	peripheral arterial occlusive disorder (see also stroke)	Phase I/II (919) 316-6300
<b>Vascugel™</b> cell therapy <b>(Orphan Drug)</b>	Pervasis Therapeutics <i>Cambridge, MA</i>	peripheral vascular disorders ----- peripheral arterial disorders	Phase II (617) 621-3407  Phase I (617) 621-3407
VM-202 (modified hepatocyte growth factor gene therapy)	ViroMed <i>Seoul, South Korea</i>	peripheral arterial disease (see also ischemic disorders)	Phase II www.viromed.co.kr

## PULMONARY VASCULAR DISEASE

Product Name	Sponsor	Indication	Development Status
<b>Aironite™</b> nitrite inhalation <b>(Orphan Drug)</b>	Aires Pharmaceuticals <i>Woburn, MA</i>	pulmonary arterial hypertension	Phase I (781) 937-0110
APD811	Arena Pharmaceuticals <i>San Diego, CA</i>	pulmonary arterial hypertension	Phase I (858) 453-7200
aviptadil (vasoactive intestinal polypeptide) <b>(Orphan Drug)</b>	Lung Rx <i>Silver Spring, MD</i>	pulmonary arterial hypertension	Phase II (301) 608-9292

## PULMONARY VASCULAR DISEASE

Product Name	Sponsor	Indication	Development Status
beraprost modified release	Lung Rx <i>Silver Spring, MD</i>	pulmonary arterial hypertension	Phase II (301) 608-9292
cell-based gene therapy	Lung Rx <i>Silver Spring, MD</i>	pulmonary arterial hypertension	Phase II (301) 608-9292
cicletanine <b>(Orphan Drug)</b>	Gilead Sciences <i>Foster City, CA</i>	pulmonary arterial hypertension	Phase II (800) 445-3235
DA-8159	Dong-A Pharmaceutical <i>Seoul, South Korea</i>	pulmonary arterial hypertension	Phase II
<b>Gleevec®</b> imatinib	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	pulmonary arterial hypertension	Phase III (888) 669-6682
macitentan	Actelion Pharmaceuticals US <i>South San Francisco, CA</i>	pulmonary arterial hypertension	Phase III (650) 624-6900
nitric oxide synthase gene therapy	MaxCyte <i>Gaithersburg, MD</i> Northern Therapeutics <i>Montreal, Canada</i>	pulmonary arterial hypertension	Phase II (301) 944-1700 (514) 842-0071
PRX-08066 <b>(Orphan Drug)</b>	PGxHealth <i>New Haven, CT</i>	pulmonary arterial hypertension	Phase II (203) 786-3400
<b>Remodulin®</b> treprostinil oral	United Therapeutics <i>Silver Spring, MD</i>	pulmonary arterial hypertension (see also ischemic disorders)	Phase III (301) 608-9292
<b>Revatio®</b> sildenafil	Pfizer <i>New York, NY</i>	pulmonary arterial hypertension in adolescents and children	Phase III (860) 732-5156
riociguat	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	chronic thromboembolic pulmonary hypertension, pulmonary arterial hypertension	Phase III (888) 842-2937
selexipag	Actelion Pharmaceuticals US <i>South San Francisco, CA</i>	pulmonary arterial hypertension	Phase III (650) 624-6900
terguride <b>(Orphan Drug)</b>	ErgoNex Pharma <i>Appenzell, Switzerland</i> Pfizer <i>New York, NY</i>	pulmonary arterial hypertension	Phase II (860) 732-5156
tezosentan	Actelion Pharmaceuticals US <i>South San Francisco, CA</i>	pulmonary arterial hypertension	Phase II (650) 624-6900

## STROKE

Product Name	Sponsor	Indication	Development Status
adult stem cell therapy	StemCyte <i>Covina, CA</i>	stroke	Phase II (866) 389-4659
betrixaban	Merck <i>Whitehouse Station, NJ</i>	prevention of stroke in patients with atrial fibrillation (see also thrombosis)	Phase II completed (800) 672-6372

## STROKE

Product Name	Sponsor	Indication	Development Status
BVI-007	BioVascular <i>San Diego, CA</i>	thrombotic stroke in patients who have had a previous cardiovascular event (see also heart attack)	Phase I (858) 455-5000
clazosentan <b>(Orphan Drug)</b>	Actelion Pharmaceuticals US <i>South San Francisco, CA</i>	vasospasm following subarachnoid hemorrhage	Phase III (650) 624-6900
desmoteplase	Lundbeck Research USA <i>Paramus, NJ</i>	ischemic stroke (Fast Track)	Phase III (201) 261-1331
DP-b99	D-Pharm <i>Rehovot, Israel</i>	stroke	Phase III www.dpharm.com
edoxaban tosylate	Daiichi Sankyo <i>Parsippany, NJ</i>	prevention of stroke (see also thrombosis)	Phase III (973) 359-2600
<b>Eliquis™</b> apixaban	Bristol-Myers Squibb <i>Princeton, NJ</i> Pfizer <i>New York, NY</i>	prevention of stroke in patients with atrial fibrillation (see also thrombosis)	application submitted (212) 546-4000 (860) 732-5156
GSK249320 (mAb)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	stroke	Phase II (888) 825-5249
GSK813893 (factor Xa inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of stroke in patients with atrial fibrillation	Phase I (888) 825-5249
ILS920	Pfizer <i>New York, NY</i>	stroke	Phase I (860) 732-5156
LU AA24493	Lundbeck USA <i>Deerfield, IL</i>	stroke	Phase I (866) 337-6996
metamfetamine	Sinapis Pharma <i>Jacksonville, FL</i>	stroke	Phase I (904) 619-0043
MP-124 (PARP inhibitor)	Mitsubishi Tanabe Pharma <i>Warren, NJ</i>	stroke	Phase I (908) 607-1950
<b>MultiStem®</b> stem cell therapy	Athersys <i>Cleveland, OH</i>	stroke (see also heart attack)	Phase I (216) 431-9900
NA-1 neuroprotectant	Arbor Vita <i>Sunnyvale, CA</i>	stroke	Phase I (408) 585-3900
Neu2000	AmKor Pharma <i>Seattle, WA</i>	stroke (see also heart attack)	Phase I www.amkorpharma.com
<b>NTx®-265</b>	Stem Cell Therapeutics <i>Calgary, Canada</i>	stroke	Phase II (403) 245-5495
PF-3049423	Pfizer <i>New York, NY</i>	stroke	Phase I completed (860) 732-5156
PL2100 (aspirin/ phosphatidyl- choline)	PLx Pharma <i>Houston, TX</i>	stroke (see also heart attack)	Phase I/II (713) 842-1249

## STROKE

Product Name	Sponsor	Indication	Development Status
rivaroxaban	Bayer HealthCare Pharmaceuticals <i>West Haven, CT</i> Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	prevention of stroke in patients with atrial fibrillation (see also acute coronary syndrome, thrombosis)	application submitted (888) 842-2937 (800) 817-5286
SAR104772	sanofi-aventis <i>Bridgewater, NJ</i>	stroke	Phase I (800) 633-1610
SUN N4057 (piclozotan)	Asubio Pharmaceuticals <i>Rochelle Park, NJ</i>	acute ischemic stroke	Phase I (201) 368-5020
TAL-0500018 (human plasma-derived fibrinolytic)	Talecris Therapeutics <i>Rsch. Triangle Park, NC</i>	stroke (see also peripheral vascular disease)	Phase I/II (919) 316-6300
<b>TNKase®</b> tenecteplase	Genentech <i>South San Francisco, CA</i>	stroke (see also thrombosis)	Phase II (800) 626-3553
TS-011	Taisho Pharmaceutical R&D <i>Morristown, NJ</i>	stroke	Phase I www.taisho.co.jp
V10153	Vernalis Pharmaceuticals <i>Morristown, NJ</i>	ischemic stroke	Phase II completed (973) 867-5555

## THROMBOSIS

Product Name	Sponsor	Indication	Development Status
AVE5026 (semuloparin)	sanofi-aventis <i>Bridgewater, NJ</i>	prevention of venous thromboembolism	Phase III (800) 633-1610
betrixaban	Merck <i>Whitehouse Station, NJ</i>	prevention of thromboembolism (see also stroke)	Phase II (800) 672-6372
BIBT986	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	thrombosis	Phase I (800) 243-0127
cangrelor	The Medicines Company <i>Parsippany, NJ</i>	prevention of coronary thrombosis (see also ischemic disorders)	Phase II (800) 388-1183
certoparin	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	prevention of thromboembolism	Phase III (888) 669-6682
clopidogrel intravenous	CyDex Pharmaceuticals <i>Lenexa, KS</i>	prevention of coronary thrombosis	Phase I (913) 685-8850 (610) 265-7710
darexaban maleate	Astellas Pharma US <i>Deerfield, IL</i>	prevention of venous thrombosis following surgery	Phase II/III (800) 727-7003
edoxaban tosylate	Daiichi Sankyo <i>Parsippany, NJ</i>	prevention of embolism, prevention of venous thromboembolism (see also stroke)	Phase III (973) 359-2600
egaptivon pegol	Archemix <i>Cambridge, MA</i>	prevention of thrombosis	Phase II (617) 621-7700

# THROMBOSIS

Product Name	Sponsor	Indication	Development Status
<b>Eliquis™</b> apixaban	Bristol-Myers Squibb <i>Princeton, NJ</i> Pfizer <i>New York, NY</i>	prevention and treatment of venous thromboembolism (see also stroke)	Phase III (212) 546-4000 (860) 732-5156
<b>Iprivask®</b> desirudin	Canyon Pharmaceuticals <i>Hunt Valley, MD</i>	prevention of thrombosis	in clinical trials (888) 434-7003
LMWH (low molecular weight heparin oral)	Emisphere Technologies <i>Cedar Knolls, NJ</i>	thrombosis	Phase I completed (973) 532-8000
MER-102 (low molecular weight heparin)	Merrion Pharmaceuticals <i>Wilmington, NC</i>	thrombosis	Phase I (910) 799-1847
NU-172	ARCA biopharma <i>Broomfield, CO</i>	thrombosis	Phase I (720) 940-2100
<b>Pradaxa®</b> dabigatran etexilate	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	prevention and treatment of venous thromboembolism (see also acute coronary syndrome)	Phase III (203) 798-9988
PSI-697	Pfizer <i>New York, NY</i>	thrombosis (see also atherosclerosis)	Phase I (860) 732-5156
REG2	Regado Biosciences <i>Basking Ridge, NJ</i>	prevention of venous thromboembolism	Phase I (908) 580-2100
rivaroxaban	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	prevention of deep vein thrombosis, pulmonary embolism and venous thromboembolism in patients undergoing hip or knee replacement surgery (see also acute coronary syndrome, stroke)	application submitted (888) 842-2937 (800) 817-5286
		prevention of systemic embolism in patients with atrial fibrillation	application submitted (888) 842-2937 (800) 817-5286
saratin	BioVascular <i>San Diego, CA</i>	thrombosis	Phase I/II (858) 455-5000
SPD 535	Shire Pharmaceuticals <i>Wayne, PA</i>	prevention of thrombosis	Phase I (800) 828-2088
TAK-442 (letaxaban)	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	thromboembolism (see also acute coronary syndrome)	Phase II (877) 582-5332
tecarfarin (ATI-5923)	ARYx Therapeutics <i>Fremont, CA</i>	prevention of thromboembolism in patients requiring chronic anticoagulation treatment	Phase II/III (510) 585-2200
terutroban sodium	Servier <i>Cedex, France</i>	prevention of thromboembolism	Phase III www.servier.com
thrombosis inhibitor (short-acting)	Bayer Healthcare Pharmaceuticals <i>Wayne, NJ</i>	thrombosis	Phase I (888) 842-2937

## THROMBOSIS

Product Name	Sponsor	Indication	Development Status
<b>TNKase®</b> tenecteplase	Genentech <i>South San Francisco, CA</i>	catheter thrombosis (see also stroke)	Phase III (800) 626-3553
UK-396082	Pfizer <i>New York, NY</i>	thrombosis	Phase I completed (860) 732-5156
vorapaxar	Merck <i>Whitehouse Station, NJ</i>	prevention of arterial thrombosis (Fast Track) (see also acute coronary syndrome)	Phase III (800) 672-6372
<b>Xigris®</b> drotrecogin alfa	Eli Lilly <i>Indianapolis, IN</i>	prevention of thrombosis in patients with end-stage renal disease on dialysis	Phase II (800) 545-5979

## OTHER

Product Name	Sponsor	Indication	Development Status
AMG 423 (omecamtiv mecarbil)	Amgen <i>Thousand Oaks, CA</i> CytoKinetics <i>South San Francisco, CA</i>	angina pectoris, cardiomyopathies (see also heart failure)	Phase II (805) 447-1000 (650) 624-3000
ART-123 (recombinant human thrombomodulin alpha)	Artisan Pharma <i>Waltham, MA</i>	disseminated intravascular coagulation	Phase II (781) 419-1919
<b>Axanum™</b> aspirin/ esomeprazole fixed-dose combination	AstraZeneca <i>Wilmington, DE</i>	prevention of cardiovascular and cerebrovascular events in patients who require continuous low-dose treatment with aspirin	application submitted (800) 236-9933
<b>CardiaPill®</b> aspirin/lisinopril/ lovastatin fixed-dose combination	CardioPharma <i>Wilmington, NC</i>	cardiovascular disorders	in clinical trials (910) 791-1361
cardiovascular therapeutic	Actelion Pharmaceuticals US <i>South San Francisco, CA</i>	cardiovascular disorders	Phase I (650) 624-6900
DB-772d	Daiichi Sankyo <i>Parsippany, NJ</i>	cardiovascular disorders	Phase I (973) 359-2600
FGF-1 (fibroblast growth factor 1)	CardioVascular BioTherapeutics <i>Las Vegas, NV</i>	angina pectoris (see also peripheral vascular disease)	Phase II (702) 248-1174
fluasterone (DHEA)	Aeson Therapeutics <i>Tucson, AZ</i>	cardiovascular disorders	Phase II (520) 748-4462
GSK2190914	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	cardiovascular disorders	Phase I (888) 825-5249

## OTHER

Product Name	Sponsor	Indication	Development Status
GSK2190915	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	cardiovascular disorders	Phase I (888) 825-5249
hypoxia therapeutic (TSC)	Diffusion Pharmaceuticals <i>Charlottesville, VA</i>	hypoxia associated with intermittent claudication in patients with peripheral arterial occlusive disorders	Phase I/II completed (434) 220-0718
ISIS 353512	Isis Pharmaceuticals <i>Carlsbad, CA</i>	cardiovascular disorders	Phase I (760) 931-9200
<b>Lantus®</b> insulin glargine	sanofi-aventis <i>Bridgewater, NJ</i>	reduction in cardiovascular morbidity and mortality	Phase III (800) 633-1610
lixivaptan	Cardiokine <i>Philadelphia, PA</i>	hyponatremia in patients with congestive heart failure	Phase III (215) 399-1200
<b>MQX-503™</b> (nitroglycerin topical)	MediQuest Therapeutics <i>Bothell, WA</i>	Raynaud's disease	Phase III (425) 398-9580
MTR105	Meditor Pharmaceuticals <i>Fort Lauderdale, FL</i>	cardiac surgery-related hypotension	Phase I (904) 501-5882
MTR107	Meditor Pharmaceuticals <i>Fort Lauderdale, FL</i>	intradialytic hypotension	Phase II (904) 501-5882
<b>Myfortic®</b> mycophenolate sodium	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	heart transplant rejection	in clinical trials (888) 669-6682
<b>Northera™</b> droxidopa <b>(Orphan Drug)</b>	Chelsea Therapeutics <i>Charlotte, NC</i>	orthostatic hypotension (Fast Track)	Phase III (704) 341-1516
		intradialytic hypotension	Phase II (704) 341-1516
PA08140	POZEN <i>Chapel Hill, NC</i>	cardiovascular disorders	Phase I (919) 913-1030
PA32540 (aspirin/ omeprazole)	POZEN <i>Chapel Hill, NC</i>	cardiovascular disorders	Phase III (919) 913-1030
PF-489791	Pfizer <i>New York, NY</i>	Raynaud's disease	Phase II (860) 732-5156
<b>Plavix™</b> clopidogrel	Bristol-Myers Squibb <i>Princeton, NJ</i> sanofi-aventis <i>Bridgewater, NJ</i>	congenital heart disorders in infants and neonates (see also acute coronary syndrome, arrhythmia)	application submitted (212) 546-4000 (800) 633-1610
<b>Revatio® IV</b> sildenafil intravenous	Pfizer <i>New York, NY</i>	cardiovascular disorders in cardiac surgery patients	Phase II (860) 732-5156
		Raynaud's disease secondary to cutaneous systemic sclerosis	in clinical trials (860) 732-5156
RG1439 (aleglitazar)	Roche <i>Nutley, NJ</i>	cardiovascular risk reduction	Phase III (973) 235-5000
RG7418 (anti-oxLDL)	Roche <i>Nutley, NJ</i>	secondary prevention of cardiovascular events	Phase I (973) 235-5000

## OTHER

Product Name	Sponsor	Indication	Development Status
RWJ-676070	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	hyponatremia (see also heart failure)	Phase I (800) 817-5286
RX-10001	Resolvix Pharmaceuticals <i>Cambridge, MA</i>	cardiovascular disorders	Phase I (781) 541-5045
<b>Sensipar®</b> cinacalcet	Amgen <i>Thousand Oaks, CA</i>	cardiovascular disease in patients with secondary hyperparathyroidism and chronic kidney disease undergoing maintenance dialysis	Phase III (805) 447-1000
SLV338	Abbott Laboratories <i>Abbott Park, IL</i>	cardiometabolic disorders	Phase I (847) 937-6100
SLx-2101	Surface Logix <i>Brighton, MA</i>	Raynaud's disease (see also hypertension)	Phase II (617) 746-8500
SRT-2104 (GSK2245840)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	cardiovascular disorders	Phase II (888) 825-5249
tafamidis meglumine <b>(Orphan Drug)</b>	FoldRx Pharmaceuticals <i>Cambridge, MA</i>	transthyretin familial amyloid cardiomyopathy	Phase III (617) 252-5500
tissue repair stem cell therapy <b>(Orphan Drug)</b>	Aastrom Biosciences <i>Ann Arbor, MI</i>	dilated cardiomyopathy (see also ischemic disorders)	Phase II (734) 930-5555
XOMA 052 (gevokizumab)	XOMA <i>Berkeley, CA</i>	cardiovascular disorders	Phase II (510) 204-7200

The content of this report has been obtained through industry sources and the Adis "R&D Insight" database based on the latest information. **Report current as of January 6, 2011.** The information in this report may not be comprehensive. For more specific information about a particular product, contact the individual company directly or go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov). The entire series of *Medicines in Development* is available on PhRMA's web site.

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**adjunctive therapy**—Auxiliary treatment that is secondary to the main treatment.

**angina pectoris**—Chest pain, usually caused by “myocardial ischemia,” a low supply of oxygen to the heart muscle resulting from hardening, narrowing, and sometimes spasm of the coronary arteries.

**angioplasty**—A technique to open up blocked coronary arteries with a catheter tube.

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

**arrhythmia**—Abnormal heart rhythm, usually detected by an electrocardiogram. Arrhythmias can be caused by several factors, such as coronary artery disease, heart valve problems or hyperthyroidism.

**arteriosclerosis obliterans**—An alternative term for **peripheral vascular disease**.

**atherosclerosis**—A common disease in which deposits of plaque containing calcium and fatty substances, such as cholesterol, are formed within the inner layers of the arteries. It is a condition that progresses over decades, chiefly affecting the arteries of the heart, brain and extremities. Its complications include heart attacks and strokes.

**atrial fibrillation** and **atrial flutter**—Very fast electrical discharge patterns that make the heart’s atria contract extremely rapidly, which causes the ventricles to contract faster and less efficiently than normal. As a result, inadequate amounts of blood are pumped out of the heart, blood pressure falls, and heart failure may occur.

**bradycardia**—A slower than normal heart rate. The heart usually beats between 60 and 100 times a minute in an adult at rest. With bradycardia, the heart beats fewer than 60 times per minute. Bradycardia can be a serious problem if the heart doesn’t pump enough oxygen-rich blood to the body. For some people, however,

bradycardia doesn’t cause symptoms or complications. An implanted pacemaker and other treatments may correct the disorder.

**bypass graft**—A vein or artery graft that bypasses blockage in an artery.

**cardiac**—Of or relating to the heart.

**cardiomyopathy**—A type of heart disease in which the heart muscle is abnormally enlarged, thickened and/or stiffened. As a result, the heart muscle’s ability to pump blood is usually impaired.

**cardiovascular**—Of or relating to the heart and blood vessels.

**coronary artery disease**—A condition caused by atherosclerosis of the arteries that supply the heart.

**critical limb ischemia**—CLI is a severe obstruction of the arteries that seriously decreases blood flow to the extremities (arms, hands, legs, feet) and has progressed to the point of severe pain and even skin ulcers of sores. The pain, called “rest pain,” caused by CLI can wake up a person at night. CLI is a very severe condition of **peripheral arterial disease** and needs comprehensive treatment by a vascular surgeon or specialist.

**deep vein thrombosis**—Blood clotting within the deep-lying veins, often in the legs or pelvic veins.

**dyslipidemia**—A condition marked by abnormal concentrations of lipids or lipoproteins in the blood.

**embolism**—The obstruction of a blood vessel by a foreign substance or a blood clot. Foreign substances that can cause embolism include an air bubble, amniotic fluid, a globule of fat, a clump of bacteria, chemicals, and drugs. Blood clots are the most common cause of embolism. The term “embolus” refers to the substance or clot that is obstructing the blood vessel, while “embolism” refers to the process by which that happens.

**genotype**—The genetic constitution (genome) of a cell, an individual, or an organism. The genotype of a person is her or his genetic makeup. It can pertain to all genes or to a specific gene.

**heart attack (myocardial infarction)**—A part of the heart muscle (myocardium) dies as a result of blood and oxygen deprivation.

**heart failure**—The end result of many different types of heart disease. The heart cannot pump blood out normally. This results in congestion (water and salt retention) in the lungs, swelling in the extremities, and reduced blood flow to body tissues.

**hemodialysis**—A medical procedure that uses a special machine (a dialysis machine) to filter waste products from the blood and to restore normal constituents to it.

**hypercholesterolemia**—The presence of an abnormally large amount of cholesterol in the cells and plasma of the circulating blood.

**hyperlipidemia**—A group of metabolic disorders characterized by high levels of lipids (fatty substances, including cholesterol) in the blood. Hyperlipidemia is a risk factor for accelerated atherosclerosis and premature heart attacks.

**hyperlipoproteinemia**—A metabolic disorder characterized by abnormally elevated concentrations of specific lipoprotein particles in the plasma.

**Hyperlipidemia** (i.e., elevated plasma cholesterol or triglyceride levels or both) is present in all hyperlipoproteinemias.

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

adenoma. In nearly all other cases (15 percent), two or more glands enlarge, again in a benign fashion, a condition called hyperplasia.

**hypertension (high blood pressure)**—Persistent elevation of blood pressure above the normal range while the heart is in **systolic** (contracting) or **diastolic** (relaxed) mode. Uncontrolled, chronic hypertension strains the heart, damages arteries and creates a greater risk of heart attack, stroke and kidney problems.

**hypertriglyceridemia**—An elevated triglyceride concentration in the blood.

**hyponatremia**—Reduced sodium concentration in the blood.

**hypotension**—A sudden fall in blood pressure. It may be caused by hypovolemia resulting from the excessive use of diuretics, vasodilators, or other types of drugs, dehydration, or prolonged bed rest. The disorder may be associated with Addison's disease, atherosclerosis (build-up of fatty deposits in the arteries), diabetes, and certain neurological disorders. Symptoms, which generally occur after sudden standing, include dizziness, light-headedness, blurred vision, and the temporary loss of consciousness.

**hypovolemia**—A deficiency in the amount of blood in the body.

**hypoxia**—An inadequate oxygen supply to the cells and tissues of the body.

**imaging agent**—A substance used to enhance images of organs and spaces in the body.

**intermittent claudication**—The most prominent symptom of **peripheral arterial disease** (PAD). It occurs in one-third to one-half of PAD patients. Claudication refers to the pain that occurs in PAD patients when they exercise, particularly during walking, which is relieved only by rest. Leg pain occurs in one leg in 40 percent of patients and in both legs in 60 percent of patients.

**ischemia**—Insufficient supply of blood to an organ or tissue, which can cause organ damage such as an **ischemic stroke**.

**lipids**—A group of fatty substances that includes triglycerides (the principal forms of fat in body fat), phospholipids (important constituents of cell membranes), and sterols (such as cholesterol).

**peripheral vascular disease**—The obstruction of blood supply to the extremities, particularly the legs, caused by atherosclerosis.

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

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

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

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

**pulmonary hypertension**—High blood pressure in the arteries supplying the lungs due to increased resistance to blood flow through the lungs.

**Raynaud's disease**—A circulatory disorder caused by insufficient blood supply to the hands and feet, resulting in cyanosis, numbness, pain, and, in extreme cases, gangrene.

**reperfusion injury**—Refers to myocardial, vascular, or electrophysiological dysfunction that is induced by the restoration of blood flow to previously ischemic tissue.

**restenosis**—A condition where an artery plugs up again following treatment to open it up.

**stent**—A metal device that is used to hold tissue in place. For example, a stent can keep blood vessels open

after a surgical procedure or heart catheterization.

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

**subarachnoid hemorrhage**—Abnormal, severe discharge of blood below or under the arachnoid membrane and the pia matter of the covering of the brain.

**supraventricular tachycardia**—An abnormally fast but regular heart rate that occurs in intermittent episodes lasting for several hours or days. It is caused by abnormal electrical impulses arising within the upper chambers of the heart taking over control of the heart beat from the heart's pacemaker (sinoatrial node).

**systemic sclerosis**—A rare chronic disease of unknown cause characterized by diffuse fibrosis, degenerative changes, and vascular abnormalities in the skin, joints, and internal organs (especially the esophagus, lower GI tract, lung, heart, and kidney). Common symptoms include Raynaud's syndrome, heartburn, and swelling and eventually skin tightening and contractures of the fingers. Lung, heart, and kidney involvement accounts for most deaths. Systemic sclerosis is about four times more common among women than men. It is most common in the third to fifth decades of life and is rare in children.

**thromboembolism**—Blockage of a blood vessel by a fragment that has broken off and been carried from a thrombus (blood clot) elsewhere in the circulation.

**thrombosis**—The formation of a blood clot within the heart or a blood vessel.

**vasospasm**—A sudden constriction of a blood vessel that reduces the blood flow.

# SELECTED FACTS ABOUT HEART DISEASE AND STROKE IN THE UNITED STATES

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## Cardiovascular Diseases (CVD)<sup>1</sup>

- More than 82 million American adults (39.9 million men; 42.7 million women)—greater than one in three—had one or more types of **CVD**. Of that total, 40.4 million were estimated to be age 60 and older.
  - The average annual rates of first major **cardiovascular** events rise from 3 per 1,000 men at ages 35-44 to 74 per 1,000 at ages 85-94. For women, comparable rates occur 10 years later in life, and the gap narrows with advancing age.
  - **CVD** (as the underlying cause of death) accounted for 33.6 percent of all 2,423,712 deaths, or 1 of every 3 deaths, in 2007. CVD total mention deaths accounted for about 55.4 percent of all deaths in 2007.
  - Nearly 2,200 Americans die of **CVD** each day, an average of one death every 39 seconds. CVD claims more lives each year than cancer, chronic lower respiratory diseases, and accidents combined.
  - More than 151,000 Americans killed by **CVD** in 2007 were under age 65.
  - The estimated direct and indirect costs of **CVD** for 2010 were \$503.2 billion.
- 

## Arrhythmias

- Millions of Americans have **arrhythmias** (disorders of heart rhythm), which are very common in older adults.<sup>2</sup>
  - About 2.2 million Americans have atrial **fibrillation/atrial flutter (AF)**, which is more common in men than women, and the most common “serious” heart rhythm increases markedly with older age.<sup>1</sup>
  - Each year, nearly 15,000 deaths and 529,000 hospital discharges are attributed to **AF**, and about 75,000 new cases of AF are diagnosed.<sup>1</sup>
  - **Stroke** is five times more likely in people with **AF** compared to those without the condition. AF is also responsible for up to 20 percent of all ischemic strokes.<sup>1</sup>
- 

## Atherosclerosis

- **Atherosclerosis** of the coronary arteries is the leading cause of death for both men and women in the United States. In men, the risk increases after age 45; in women, the risk increases after age 55.<sup>2</sup>
  - In 2007, **atherosclerosis** accounted for 8,232 deaths and 123,000 hospitalizations.<sup>1</sup>
- 

## Coronary Heart Disease (CHD)<sup>1</sup>

*(Heart Attack, Angina Pectoris, or both)*

- In 2007, 16.3 million American adults (age 20 and older) suffered from **coronary heart disease** (8.8 million men; 7.5 million women). Annually, 1.255 million people are diagnosed with CHD (740,000 men; 515,000 women), which caused one of every six deaths in 2007.
- **Acute coronary syndrome**—defined as patients who have either acute myocardial infarction or unstable angina—accounted for 671,000 hospital discharges in 2007.
- An estimated 9 million people in the United States suffer from **angina** (4 million men; 5 million women), and some 500,000 new cases of **stable angina** occur each year.
- About every 34 seconds, an American will suffer a **heart attack**. The estimated annual incidence of heart attack (**myocardial infarction, MI**) is 610,000 new attacks and 325,000 recurrent attacks annually. In addition, some 195,000 silent first heart attacks occur annually.
- In 2007, **MI** caused 132,968 deaths (71,712 men; 61,256 women). The average age of a person having a first heart attack is 64.5 for men and 70.3 for women.
- The estimated direct and indirect costs of **CHD** for 2010 were \$177.1 billion.

# SELECTED FACTS ABOUT HEART DISEASE AND STROKE IN THE UNITED STATES

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## Heart Failure (HF)<sup>1</sup>

- Of the 5.7 million adults living with **heart failure (HF)**, 3.1 million are men and 2.6 million are women. **High blood pressure** precedes 75 percent of HF cases.
  - Survival after **HF** diagnosis has improved, but the death rate remains high—50 percent of people diagnosed with HF will die within five years. In 2007, HF was listed as the underlying cause in 56,565 deaths.
  - The estimated direct and indirect costs of **HF** for 2010 were \$39.2 billion.
- 

## Hypertension<sup>1</sup>

(High Blood Pressure—HBP)

- In 2008, 76.4 million adults (36.5 million men; 39.9 million women) had **high blood pressure (HBP)**. One in three adults has HBP. About 69 percent of people who have a first **heart attack**, 77 percent who have a first **stroke**, and 74 percent with **congestive heart failure** have blood pressure higher than 140/90 mm Hg.
  - A higher percentage of men than women have **HBP** until age 45. From ages 45-54, the percentage of men and women is similar. After that, a much higher percentage of women have HBP than men do.
  - The prevalence of **HBP** in African Americans is among the highest in the world, and it is increasing. Compared with whites, blacks develop HBP earlier in life and their average blood pressures are much higher. As a result, blacks have a 1.3 times greater rate of **nonfatal stroke**, a 1.8 times greater rate of **fatal stroke**, a 1.5 times greater rate of heart disease death, and a 4.2 times greater rate of end-stage kidney disease.
  - In 2007, **HBP** was responsible for 57,732 deaths (24,984 males; 32,748 females). That year, the death rates for HBP were 15.7 for white males, 49.2 for black males, 14.3 for white females, and 37.0 for black females.
  - The estimated direct and indirect costs of **HBP** for 2010 were \$76.6 billion.
- 

## Lipid Disorders<sup>1</sup>

- Among adolescents ages 12-19, the mean total blood **cholesterol** level is 159.2 mg/dL. About 8.5 percent of adolescents in that age group have total cholesterol levels equal to or exceeding 200 mg/dL.
  - The 2008 estimated prevalence of total **cholesterol** in adults age 20 and older at or above 200 mg/dL was 98.8 million (45 million men; 53.8 million women).
- 

## Peripheral Vascular Disease<sup>3</sup>

- **Peripheral arterial disease (PAD)** affects more than 8 million Americans and is considered a leading indicator for those at risk of stroke and heart disease.
  - **PAD** can happen to anyone, regardless of age, but it is most common in men and women over age 50 and disproportionately affects African Americans. It affects 12 percent to 20 percent of Americans age 65 and older.
  - Only 10 percent of people with **PAD** have the classic symptoms of **intermittent claudication** (intermittent leg pain).
- 

## Risk Factors

- In the United States, 23.6 million children and adults—7.8% of the population—have **diabetes**. Of that total, 17.9 million people have been diagnosed with the disease, while 5.7 million people are undiagnosed. Each year, 1.6 million new cases of diabetes are diagnosed in people ages 20 and older. Under age 20, 186,300, or 0.22% of all people in this age group, have diabetes. About 1 in every 400 to 600 children and adolescents has type 1 diabetes.<sup>4</sup>
- Adults with **diabetes** have **heart disease** death rates about two to four times higher than adults without diabetes, and the risk for **stroke** is two to four times higher among people with diabetes. In 2004, heart disease was noted on 68 percent of diabetes-related death certificates among people ages 65 or older, while stroke was noted on 16 percent of diabetes-related death certificates among people in that age group.<sup>4</sup>

# SELECTED FACTS ABOUT HEART DISEASE AND STROKE IN THE UNITED STATES

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## Risk Factors (continued)

- Nearly 10 million children and adolescents ages 6-19 are considered **overweight**. The prevalence of overweight in children ages 6-11 increased from 4 percent between 1971-74 to 17 percent between 2003-2006. Overweight adolescents have a 70 percent chance of becoming overweight adults. That increases to an 80 percent chance if one or both parents are overweight or obese.<sup>4</sup>
  - In 2006, an estimated 144.1 million U.S. adults (age 20 and older) were **overweight** or **obese** (75.5 million men; 68.6 million women), representing 66.3 percent of the adult population. That year, an estimated 71.6 million U.S. adults (age 20 and older) were obese (33.6 million men; 38 million women), representing about 32.9 percent of the adult population.<sup>4</sup>
  - According to one study, annual medical spending on **overweight** and **obesity** could be as high as \$147 billion in 2008 dollars, which would represent almost 10 percent of U.S. health expenditures.<sup>4</sup>
  - In 2009, the estimated prevalence for **smoking** among people ages 18 and older was 46.6 million. From 2000 to 2004, cigarette smoking resulted in an estimated 443,000 premature deaths each year from smoking-related illnesses, and about 49,000 of those deaths were from secondhand smoke.<sup>1</sup>
  - Cigarette **smokers** are two to four times more likely to develop CHD than nonsmokers and are more than 10 times as likely as nonsmokers to develop peripheral vascular disease.<sup>1</sup>
  - Direct medical costs (\$96 billion) and lost productivity costs (\$97 billion) associated with **smoking** total an estimated \$193 billion per year between 2000 and 2004.<sup>1</sup>
- 

## Stroke<sup>1</sup>

- On average, someone in this country has a **stroke** every 40 seconds. An estimated 7 million Americans (2.8 million men; 4.2 million women) have suffered a stroke, and each year about 795,000 people experience a new or recurrent stroke.
  - African Americans have almost twice the risk of first-ever **stroke** compared with whites. The age-adjusted stroke incidence rates at ages 45 to 84 are 6.6 per 1,000 population in black men, 3.6 in white men, 4.9 in black women and 2.3 in white women.
  - Because women live longer than men and **stroke** occurs at older ages, more women than men die of stroke each year. Women accounted for 60.2 percent of U.S. stroke deaths in 2007.
  - On average, every four minutes someone dies of a **stroke**. In 2008, stroke ranked as the fourth leading cause of death behind diseases of the heart, cancer and chronic lower respiratory diseases, after being the third for more than 50 years.
  - The estimated direct and indirect costs of **stroke** for 2010 were \$73.7 billion.
- 

## Thrombosis<sup>1</sup>

- **Pulmonary embolism (PE)** accounted for 7,097 deaths in 2007 in the United States and accounted for 146,000 hospital discharges that same year.
  - In 2007, 2,381 Americans died from **deep vein thrombosis (DVT)**.
- 

## Sources:

1. *Heart Disease and Stroke Statistics—2010 Update*, American Heart Association, [www.heart.org](http://www.heart.org)
2. National Heart, Lung and Blood Institute, [www.nhlbi.nih.gov](http://www.nhlbi.nih.gov)
3. HealthYes®! [www.healthyes.com](http://www.healthyes.com)
4. American Diabetes Association [www.diabetes.org](http://www.diabetes.org)

## THE DRUG DISCOVERY, DEVELOPMENT AND APPROVAL PROCESS

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

Discovery/ Preclinical Testing		Clinical Trials			FDA	Phase IV
		Phase I	Phase II	Phase III		
<b>Years</b>	6.5	1.5	2	3.5	1.5	
<b>Test Population</b>	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
<b>Purpose</b>	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		
<b>Success Rate</b>	5,000 compounds evaluated	5 enter trials			1 approved	

## THE DRUG DEVELOPMENT AND APPROVAL PROCESS

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

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

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

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

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

**Investigational New Drug Application (IND).** After completing preclinical testing, a company files an IND with the U.S. Food and Drug Administration (FDA) to begin to test the drug in people. The IND shows results of previous experiments; how, where and by whom the new studies will be conducted; the chemical structure of the compound; how it is thought to work in the body; any toxic effects found in the animal studies; and how the compound is manufactured. All clinical trials must be reviewed and approved by the Institutional Review Board (IRB) where the trials will be conducted. Progress reports on clinical trials must be submitted at least annually to FDA and the IRB.

**Clinical Trials, Phase I.** These tests usually involve

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

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

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

**New Drug Application (NDA)/Biologic License Application (BLA).** Following the completion of all three phases of clinical trials, a company analyzes all of the data and files an NDA or BLA with FDA if the data successfully demonstrate both safety and effectiveness. The applications contain all of the scientific information that the company has gathered. Applications typically run 100,000 pages or more. The average review time for the 25 new therapeutics approved by the FDA in 2009 was 13.3 months.

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

Discovering and developing safe and effective new medicines is a long, difficult, and expensive process. Pharmaceutical companies invested an estimated \$65.3 billion in research and development in 2009.

## TRACKING THE PHARMACEUTICAL AND BIOTECHNOLOGY RESEARCH PIPELINES

Today, more than 2,900 new medicines are in development in the United States. Many of these potential new medicines will fail in clinical trials, but some may represent tomorrow's new treatments. Bringing each new medicine to patients will require, on average, 10 to 15 years of testing and review.

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

- **Cancer**—There are few things that cause patients more fear and uncertainty as a cancer diagnosis. Yet today—because of a steady stream of new and improved medicines and treatments—cancer can increasingly be managed and even beaten. *The 2009 report found 861 medicines in the pipeline.*
- **Alzheimer's Disease**—Today, more than 5 million Americans are suffering from Alzheimer's disease, robbing them of their independence and even their identity. The disease ravages the minds of patients, crushes entire families, and currently costs the health care system \$172 billion a year—or 18 times more than the national cost of providing school lunches to poor children. These sobering statistics are projected to get much worse as America's 76 million baby boomers begin turning 65 this January. *The 2010 report found 98 medicines in the pipeline.*
- **Diabetes**—Approximately 4,110 people are diagnosed with diabetes every day. To help fight this disease, pharmaceutical and biotechnology researchers are working on new medicines to treat it and related conditions. *The 2010 report found 235 medicines in the pipeline.*
- **Mental Illnesses**—Pharmaceutical and biotechnology researchers are testing many new medicines to help the more than 450 million people worldwide who suffer from some form of mental illness. *The 2010 report found 313 medicines in the pipeline.*
- **Biotechnology**—Millions of people have already benefited from medicines and vaccines developed through biotechnology, and a new report offers hope that many more will benefit in the future. *The 2008 report found 633 medicines in the pipeline.*
- **Children**—Biopharmaceutical researchers are testing medicines to meet the special needs of children. These medicines offer hope that the significant improvements achieved in children's health over the past few decades will continue and even accelerate. *The 2010 report found 234 medicines in clinical trials.*
- **Older Americans**—The population of Americans over 65 is surging, and the pace will only increase over the coming years. As life expectancy continues to expand, older Americans face new and growing challenges to their health, productivity and independence. *The 2008 report found 1,026 medicines in the pipeline.*



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