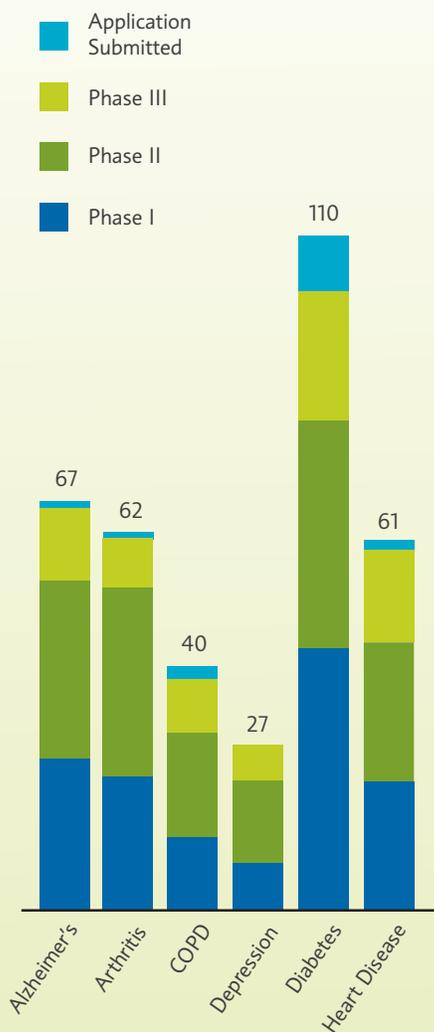


MEDICINES IN DEVELOPMENT FOR

# Older Americans

THE MEDICARE POPULATION AND LEADING CHRONIC DISEASES

## Medicines in Development For Leading Chronic Diseases Affecting Seniors



Some medicines are listed in more than one category.

## Biopharmaceutical Research Companies Are Developing More Than 430 Medicines for Top Chronic Diseases Affecting Older Americans

As life expectancy continues to climb—up to more than 81 years for women and 76 years for men—the growing number of Americans age 65 and older will face new challenges from chronic conditions such as arthritis, Alzheimer’s disease, cardiovascular disease and diabetes, which impact their health, productivity and independence. Those diseases not only impact the individuals living with them, but burden their families and cost the health care system billions of dollars.

Biopharmaceutical research companies are developing 435 medicines targeting 15 leading chronic conditions affecting seniors—Alzheimer’s and dementia, anemia, arthritis, benign prostatic hyperplasia, cataracts and glaucoma, chronic kidney disease, chronic obstructive pulmonary disease (COPD), depression, diabetes, heart failure, hyperlipidemia, hypertension, hypothyroidism and ischemic heart disease.\* The medicines in the pipeline build on the progress to

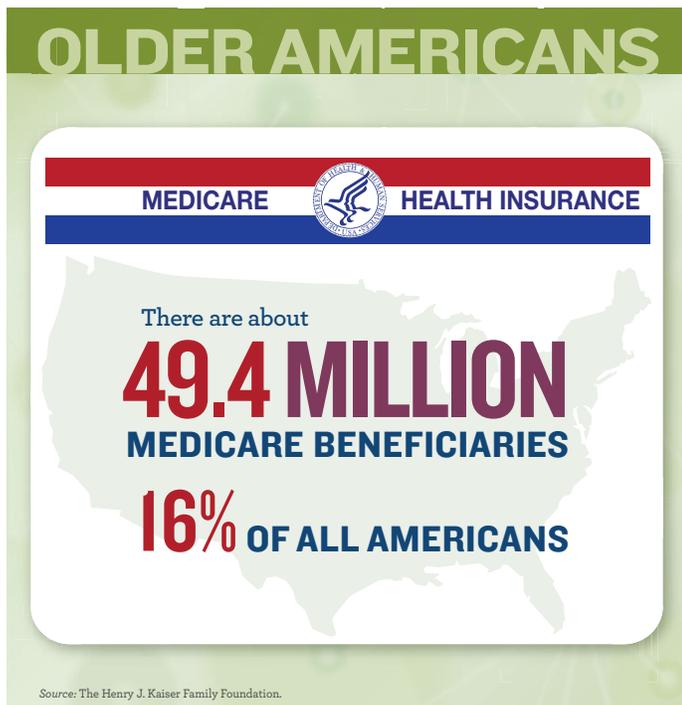
date and hold the potential to further improve health outcomes and provide cost savings. All of the medicines in this report are either in clinical trials or under review by the U.S. Food and Drug Administration (FDA). The 435 medicines in development include:

- 110 for diabetes, which affects 10.9 million Americans age 65 and older.
- 67 for Alzheimer’s disease, which could affect 15 million people in the United States by 2050 if no new medicines are found to prevent, delay or stop the progression of the disease.

### Contents

Medicines in the Pipeline .....	2
Healthy Aging: Treatment Advances .....	3
Better Outcomes Through Adherence .....	4
Medicare Part D Delivering Results .....	5
Facts About Chronic Diseases in the United States .....	9
Medicines in Development Chart .....	11
Glossary .....	42
Drug Development/ Approval Process .....	47

\* Centers for Medicare and Medicaid Services (CMS), Chronic Condition Data Warehouse (CCW), Medicare, 2012. The CCW counts reflect fee-for-service administrative claims only of Medicare beneficiaries. [www.ccwdata.org/web/guest/medicare-tables-reports](http://www.ccwdata.org/web/guest/medicare-tables-reports)



- 62 for rheumatoid arthritis and osteoarthritis, which affect 1.5 million and 27 million Americans, respectively.
- 61 for heart disease—atrial fibrillation, heart failure, hypertension, ischemic heart disease and high cholesterol.
- 40 for COPD, which affects about 13 million adults, with the highest prevalence rate in those over age 65.

Research and development of new medicines is a long and risky road, where tens of thousands of compounds in early development result in only one approved for patients. Even medicines that reach clinical trials have only a 16 percent chance of being approved. Even though the stakes are high, the 435 medicines in this report provide hope to older Americans who live with these debilitating chronic diseases and are seeking to live longer, more independent and healthier lives.

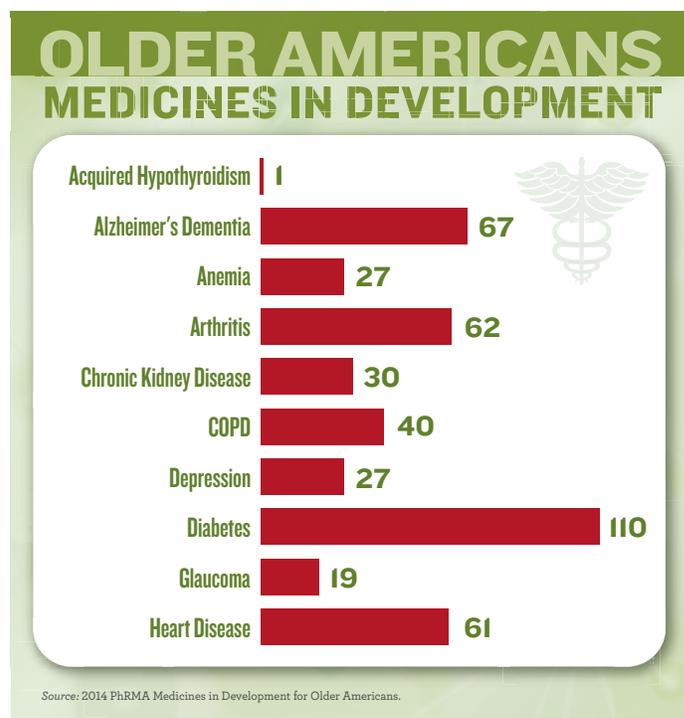
## Medicines in the Pipeline

Many medicines in development today target the most common chronic conditions affecting Medicare beneficiaries—high blood pressure, high cholesterol, heart disease, arthritis and

diabetes. Some of these potential medicines utilize expanded knowledge and cutting-edge technology to attack diseases in different ways, and many offer new ways to treat or prevent disease. Examples of the medicines being developed for some of the most common chronic conditions include:

**Recombinant Treatment for Heart Failure**—A medicine in development for heart failure, a condition with lower survival rates than those of some advanced cancers or heart attack, is a recombinant form of a naturally occurring hormone that is present in both men and women. The potential medicine works by relaxing blood vessels and reducing fluid buildup, and some evidence suggests that it can also reduce damage to the heart and other vital organs related to the cascade of damage associated with heart failure.

**Blocking a Protein to Lower LDL Cholesterol**—Several monoclonal antibodies in development represent a potential new class of lipid-lowering treatments. The potential medicines inhibit a protein that targets low-density lipoprotein (LDL) receptors on the surface of the liver. When that protein interacts with LDL receptors, it promotes degradation of the receptor, ultimately, interfering with the clearing of LDL-C (LDL cholesterol) from the blood. By blocking the protein



from interacting with the receptor, more LDL receptors are available on the surface of liver cells to remove LDL-C from the blood.

**Next-Generation Oral Treatment for Type 2 Diabetes**—A medicine in development for the treatment of type 2 diabetes is part of the dipeptidyl peptidase 4 (DPP-4) inhibitor class, with properties distinct from other approved medicines in this class. DPP-4 inhibitors work by stimulating the secretion of insulin and decreasing the release of glucagon (a hormone produced in the pancreas), ultimately reducing blood glucose levels. In clinical trials, the medicine was able to inhibit more than 80 percent of DPP-4 for seven days, making it potentially a once-weekly versus daily treatment.

**Inhibiting Beta-Amyloid Production in Alzheimer's Disease**—A potential first-in-class medicine inhibits beta-site amyloid precursor protein cleaving enzyme (BACE), an enzyme involved in the production of beta-amyloid peptide. Beta-amyloid is believed to be involved in Alzheimer's disease.

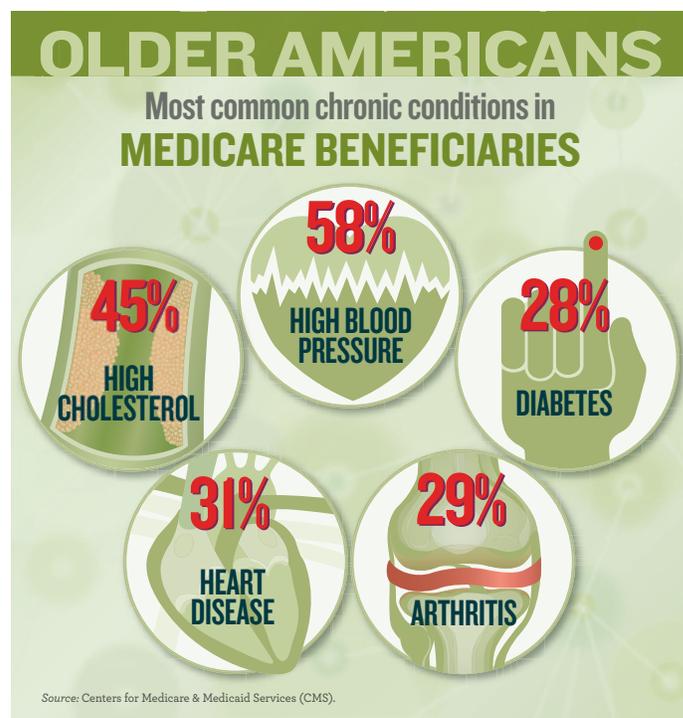
**Cartilage Regeneration for Osteoarthritis**—An allogeneic (donor) cell therapy being studied in clinical trials uses a mixture of cartilage cells that have been genetically modified to produce the growth factor TGF- $\beta$ 1 (transforming growth factor beta 1) and unmodified cells. TGF- $\beta$ 1 plays a critical role in the development, growth, maintenance and repair of cartilage in bone joints (articular cartilage) by stimulating chondrocytes (mature cells found in cartilage). In clinical trials, cartilage regeneration by the modified cells has shown to be significantly enhanced by the co-delivery of unmodified cells at the site of degeneration. The medicine, delivered through local injection, may potentially treat not only the symptoms of osteoarthritis but also the causes, by promoting the regeneration of cartilage.

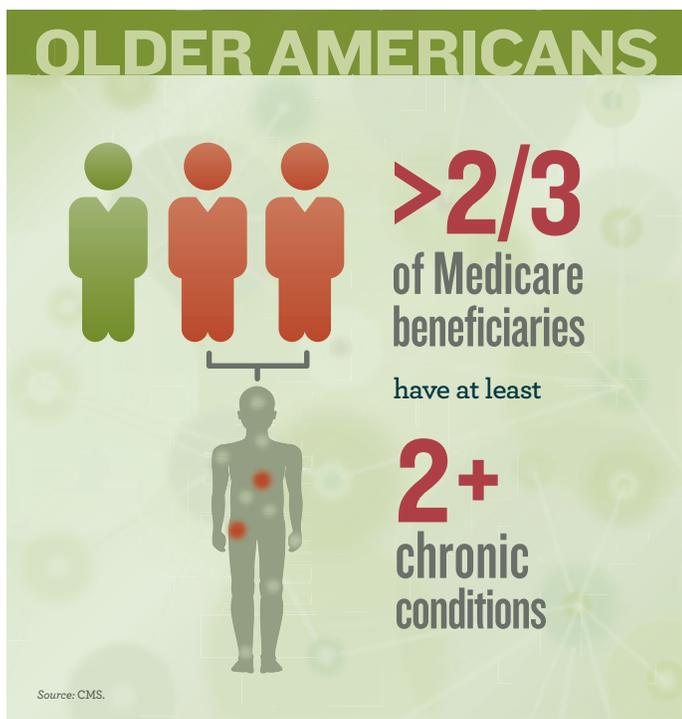
## Healthy Aging: Treatment Advances

The medicines in the pipeline today follow decades of advances in discovery and development of innovative therapies. In the last decade, more than 300 new medicines have been approved by the FDA, including a new class of medicines to

treat high blood pressure, the first therapeutic cancer vaccine, two new personalized medicines for skin cancer, and three new treatments for diabetes. Those medicines and others are transforming many diseases into treatable conditions and reducing the impact of chronic diseases like cardiovascular disease, diabetes, osteoporosis and rheumatoid arthritis. In addition, health outcomes continue to improve, with the use of new medicines playing a large role in achieving better results.

- **Life expectancy** for men and women has increased by a full decade since 1950, from 68.2 to 78.7 years of age in 2011, according to the U.S. Centers for Disease Control and Prevention (CDC).
- The **death rate for Americans has fallen** by 60 percent in the last 75 years, reaching a record low in 2011 and almost a full percent lower than in 2010, according to the CDC.
- **Death rates from cardiovascular disease fell** more than 55 percent between 1979 and 2011, according to the CDC. The CDC cites factors contributing to the decline in heart disease and stroke deaths including better control of risks factors, early detection, and better treatment and care, as well as new drugs and expanded use of existing drugs.





- **Disability among seniors is down**—a Harvard University study found that between 1984 and 2004/05, disability in the elderly decreased by one-fifth. In that same period, an elderly patient’s ability to survive a cardiovascular event without becoming disabled rose by 50 percent.
- **Better outcomes in rheumatoid arthritis** are achieved when treatment is initiated earlier in the disease, according to a report from Boston Healthcare Associates. Long-term data analysis found that 46 percent of patients who received treatment earlier in disease achieved remission compared to only 31 percent of patients treated at an advanced stage.

## Better Outcomes through Adherence

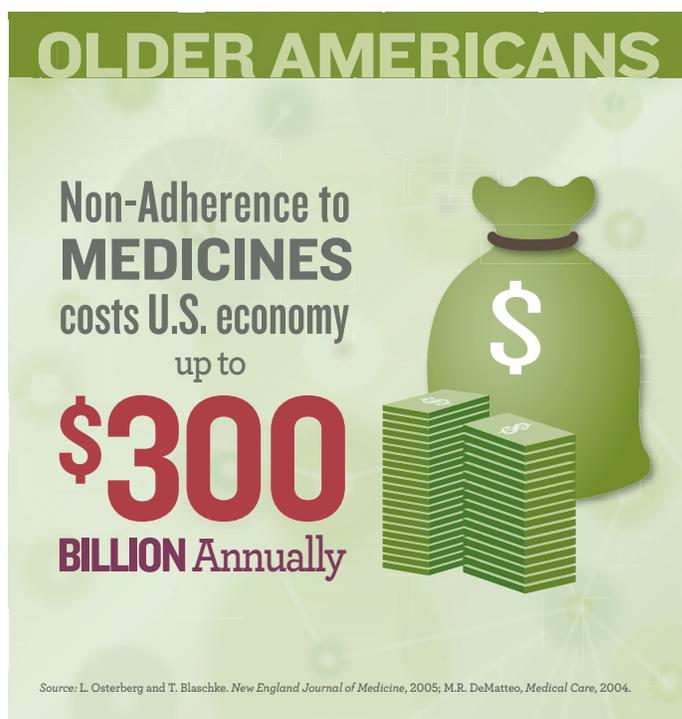
Research has shown that better and continued use of medicines as prescribed lead to better health outcomes. Several studies have illustrated the positive impact that better adherence to medicines can have on the health of patients and the U.S. economy.

- Diabetes patients who take their medicine as prescribed have fewer diabetes-related complications, such as amputation/ulcers (4 percent lower than nonadherent patients), renal events (5 percent lower), neuropathy (4 percent lower),

“Factors contributing to the decline in heart disease and stroke deaths include better control of risk factors, improved access to early detection, and better treatment and care, including new drugs and expanded uses for existing drugs.”—*CDC*

and retinopathy (2.7 percent lower), according to a study published in the *American Journal of Managed Care*.

- Improved adherence to medication among diabetes patients could prevent more than 1 million emergency department visits and hospitalizations annually, potentially saving \$8.3 billion each year, according to a study published in *Health Affairs*.
- A study published in *Health Affairs* found that if untreated hypertension patients received the recommended treatment, potentially 420,000 hospitalizations and 89,000 premature deaths could be avoided each year. A separate study published in the *Journal of General Internal Medicine* found that better adherence to antihypertensive medicines could save about 200,000 lives over five years.



## OLDER AMERICANS



**IMPROVED Adherence** = **Better Health AND Fewer Hospital ADMISSIONS**

Source: L. Osterberg and T. Blaschke, *New England Journal of Medicine*, 2005.

- According to a study published in the *American Journal of Managed Care*, Medicare will realize more than \$26.9 billion in savings from 2013-2022, driven by reductions in Part A and B expenditures associated with improved congestive heart failure (CHF) medication adherence following the implementation of Part D. Achieving recommended levels of adherence (proportion of days covered of 80 percent or higher) among Part D enrollees with CHF could yield \$22.4 billion in federal savings through 2022.
- Following implementation of Part D, monthly Medicare Part A and B spending was 10 percent to 12 percent lower for high adhering patients taking statins, ACE inhibitors (ACEI) and angiotensin receptor blockers (ARB), according to a study published in *Health Services Research*. The same savings were not observed for nonadherent beneficiaries.

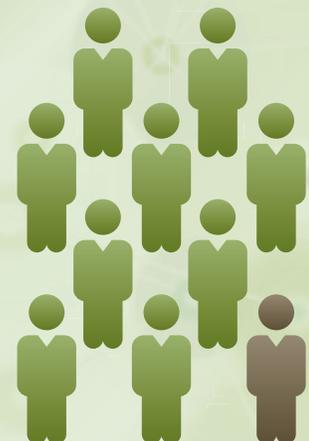
### Medicare Part D Delivering Results

Just as adherence to medicines is essential to the successful prevention, management and treatment of disease, access to a range of medicines across therapeutic categories is critical to maintaining the improved health outcomes and cost savings we have seen in recent years. The Medicare prescription drug program (Part D) is answering that call with great results.

Now in its ninth year, Medicare Part D continues to exceed expectations. An extensive body of research attests to the program's successes.

- Ninety percent of Medicare beneficiaries receive comprehensive prescription drug coverage. Even more, 90 percent of Part D enrollees are satisfied with their coverage, according to a 2012 *Medicare Today* survey.
- Part D represented only 10% of Medicare spending in 2012, according to the Congressional Budget Office (CBO).
- The Congressional Budget Office (CBO) recently reduced its 10-year forecast for Part D spending by \$56 billion. That reduction follows three consecutive years of 10-year spending reductions by more than \$100 billion.
- Based on a sizable body of research, the CBO has recently adopted an historic scoring change that will credit Medicare policies that increase the use of medicines with savings on other Medicare costs.
- Harvard researchers report savings on hospital and skilled nursing facility costs of about \$1,200 per newly insured Part D beneficiary in 2007. That equals overall Medicare

## OLDER AMERICANS MEDICARE PART D SUCCESS

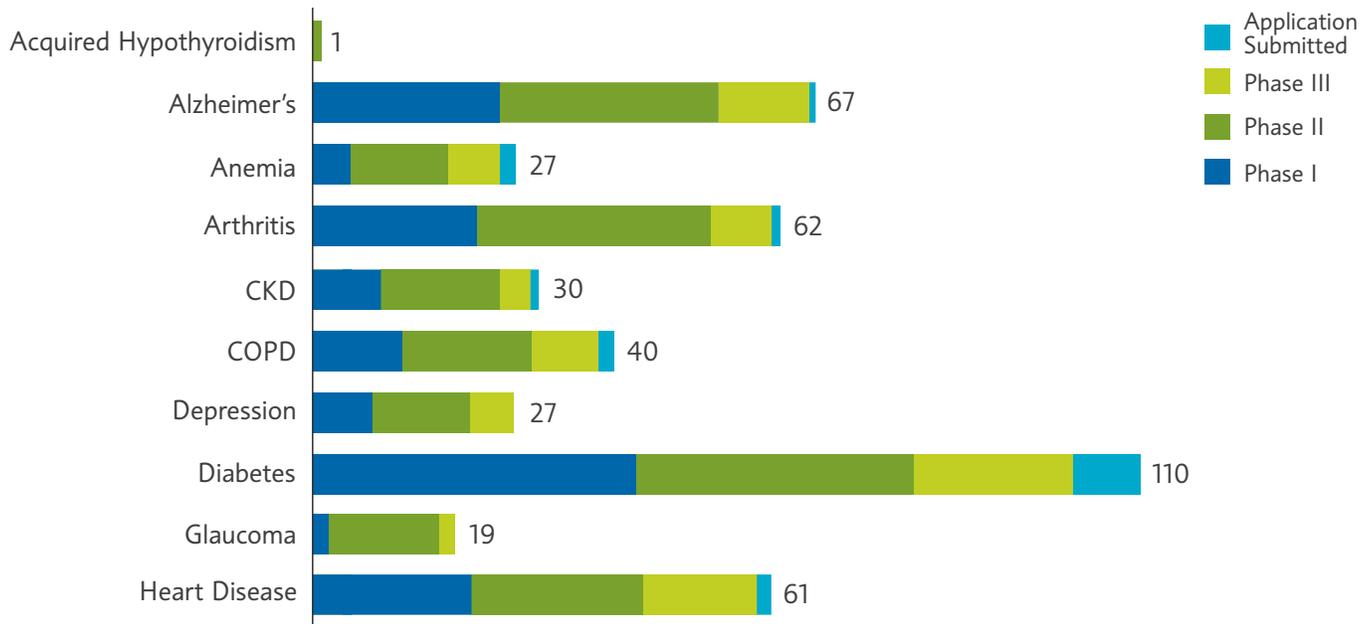


**90%**  
of beneficiaries  
**ARE SATISFIED**  
with the program

Source: Congressional Budget Office (CBO).

## Medicines in Development By Disease and Phase

Some medicines are listed in more than one category.

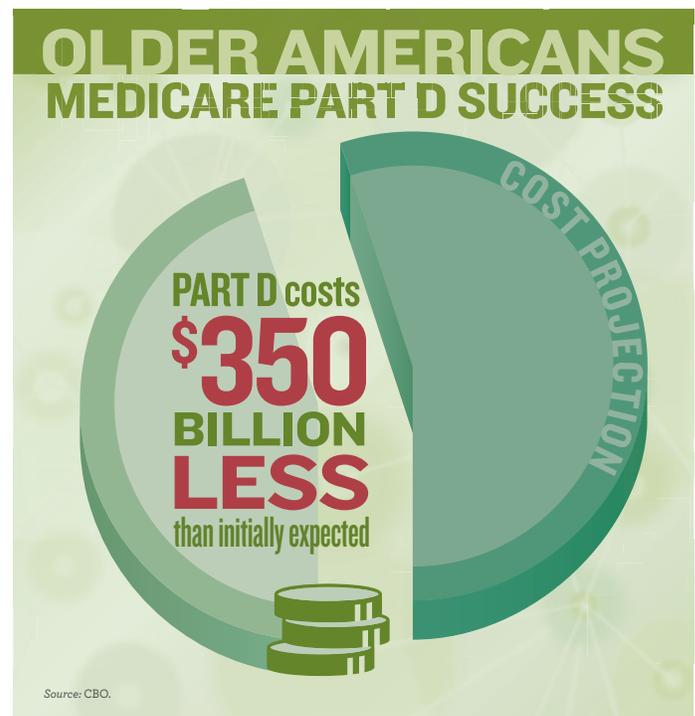


savings of \$13.4 billion, more than one-fourth of Part D's total cost during its first full year.

- According to a study published in *Health Affairs*, every additional dollar spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes and high cholesterol generated \$3 to \$10 in savings on emergency room visits and hospitalizations.

Part D has been a success for seniors and taxpayers due to its market-based, competitive structure, in which prices are negotiated by large private plans—the same plans used by corporate employers and insurers—on behalf of seniors and taxpayers.

Medicare Part D stands as an example of how a market-based health care program runs efficiently and delivers the services and treatments it promised. The more than 435 medicines in the pipeline targeting myriad chronic diseases provide new hope to older Americans seeking to live longer, more independent and healthier lives. Programs such as Medicare Part D help ensure that seniors have access to the medicines they need to prevent, manage and treat disease.



## Selected Facts About Chronic Diseases Affecting Older Americans

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

- An estimated 5.4 million Americans have **Alzheimer's disease (AD)**. Today, someone in America develops AD every 68 seconds. By 2050, there is expected to be one new case of AD every 33 seconds, or nearly a million new cases per year, and AD prevalence is projected to be 11 million to 16 million.
- **AD** is the sixth leading cause of death in the United States and the fifth leading cause of death in Americans age 65 and older.
- Medicare payments for services to beneficiaries age 65 and older with **AD** and other dementias are three times as great as payments for beneficiaries without those conditions, and Medicaid payments are 19 times as great. In 2012, payments for health care, long-term care, and hospice services for people age 65 and older with AD and other dementias were estimated to be \$200 billion (not including the contributions of unpaid caregivers, which were valued at more than \$210 billion).

### Anemia<sup>2</sup>

- The frequency of **anemia** varies depending on age, sex, and overall health. For older adults, age 65 years and over, around 10 percent have anemia. For older adults residing in a nursing-home, about 50 percent have anemia.

### Arthritis

- Some 52.5 million U.S. adults suffer from **arthritis**.<sup>3</sup> From 2010-2012, 49.7 percent of adults age 65 or older reported an arthritis diagnosis.<sup>4</sup>
- About 27 million people in America have **osteoarthritis**. Common risk factors include increasing age, obesity, previous joint injury, overuse of the joint, weak thigh muscles, and genetics.<sup>3</sup>
- About 1.5 million people in the United States have **rheumatoid arthritis (RA)**. Nearly three times as many women have the disease as men. In women, RA most commonly begins between ages 30 and 60. In men, it often occurs later in life.<sup>3</sup>

- In 2009, there were 15,600 hospitalizations with **RA** listed as the principal diagnosis with total hospital charges of \$545 million (mean charge of \$35,000 per person). Women and people ages 45 and older accounted for the majority of those stays.<sup>4</sup>

### Cataracts<sup>5</sup>

- Most **cataracts** are related to aging and are very common in older people. By age 80, more than half of all Americans either have a cataract or have had cataract surgery. People can have an age-related cataract in their 40s and 50s, but during middle age, most cataracts are small and do not affect vision. It is after age 60 that most cataracts steal vision.

### Chronic Condition Co-Morbidity

- Nearly 92 percent of older adults have at least one **chronic condition**, and 77 percent have at least two.<sup>6</sup>
- Four **chronic conditions**—heart disease, cancer, stroke, and diabetes—cause almost two thirds of all deaths each year.<sup>6</sup>
- **Stroke** and **heart failure** are highly co-morbid conditions with about 55 percent of Medicare beneficiaries with those conditions having 5 or more other chronic conditions.<sup>7</sup>
- **High cholesterol** was the most common chronic condition among beneficiaries with at least 2 chronic conditions, while **stroke** was the most common condition among the costliest co-occurring conditions.<sup>7</sup>
- Among beneficiaries with at least three chronic conditions, **high cholesterol** and **high blood pressure** were the most prevalent, and **stroke** and **chronic kidney disease** were the costliest.<sup>7</sup>

### Chronic Kidney Disease

- **Chronic kidney disease (CKD)** affects 26 million American adults and millions of others are at increased risk.<sup>8</sup> The chance of having CKD increases after age 50 and is most common among adults older than age 70.<sup>4</sup>

- Approximately 1 in 3 adults with **diabetes** and 1 in 5 adults with **high blood pressure** have CKD. Other risk factors for CKD include cardiovascular disease and high cholesterol, which are risk factors more common in older age.<sup>4</sup>
- **Diabetes** and **hypertension** also are the leading causes of **end-stage renal disease (ESRD)**. In 2011, diabetes or hypertension was listed as the primary cause for 7 of 10 new cases of ESRD in the United States, which is more common among adults over age 70.<sup>4</sup>

### Chronic Obstructive Pulmonary Disease<sup>9</sup>

- An estimated 12.7 million U.S. adults have been diagnosed with **chronic obstructive pulmonary disease (COPD)** [emphysema and chronic bronchitis]; however, research has indicated that COPD is underdiagnosed and that up to 24 million Americans have evidence of impaired lung function.
- In 2011, 4.7 million Americans reported ever being diagnosed with **emphysema**, a lifetime prevalence rate of 20.2 per 1,000 people. More than 90 percent of emphysema cases were in individuals over the age of 45.
- More than 10 million Americans reported a physician diagnosis of **chronic bronchitis** in 2011 with almost 70 percent of cases occurring in those over age 45. Prevalence rates increased with age; they were lowest among those 18-44 (28.6 per 1,000 people) and highest among those age 65 and older (64.2 per 1,000 people).
- **COPD** is an important cause of hospitalization in the U.S. older population. Approximately 65 percent of hospital discharges were in the age 65 and older population in 2010. The discharge rate for the population over age 65 (114.1 per 10,000 people) was more than four times higher than that in the 45-64 age group (28.6 per 10,000 people).
- COPD takes a heavy toll on our economy. The national projected annual cost for COPD in 2010 was \$49.9 billion. That included \$29.5 billion in direct health care expenditures, \$8.0 billion in indirect morbidity (lost productivity due to illness) costs and \$12.4 billion in indirect mortality (productivity lost due to early death) costs.

### Depression

- **Depression** affects more than 6.5 million of the 35 million Americans age 65 years and older. Most people in this stage of life with depression have been experiencing episodes of the illness during much of their lives. For others, depression has a first onset in late life—even people in their 80s and 90s.<sup>10</sup>
- **Depression** is the single most significant risk factor for suicide in the elderly population.<sup>10</sup> The population over age 65 accounts for more than 25 percent of the nation's suicides. White men over age 80 are six times more likely to commit suicide than the general population.<sup>11</sup> Older women are at a greater risk for suicide because women in general are twice as likely as men to become seriously depressed.<sup>10</sup>

### Diabetes<sup>12</sup>

- A total of 25.8 million children and adults in the United States—8.3 percent of the population—have **diabetes**. Of that total, 10.9 million are age 65 or older. That's 26.9 percent of all people in that age group who have diabetes.
- The total costs of diagnosed **diabetes** in the United States in 2012 were \$245 billion: \$176 billion for direct medical costs and \$69 billion in reduced productivity.

### Glaucoma<sup>13</sup>

- Everyone is at risk for **glaucoma** from babies to senior citizens. Older people are at a higher risk for glaucoma, but babies can be born with glaucoma (approximately 1 out of every 10,000 babies born in the United States).
- More than 2.2 million Americans are estimated to have **glaucoma**, but only half of them know they have it.
- In the United States, more than 120,000 are blind from **glaucoma**, accounting for up to 12 percent of all cases of blindness.
- In terms of Social Security benefits, lost income tax revenues, and health care expenditures, **glaucoma** costs the U.S. government more than \$1.5 billion annually.

## Heart Failure

- **Heart failure (HF)** has been singled out as an epidemic and is a staggering clinical and public health problem, associated with significant mortality, morbidity, and health-care expenditures, particularly among those ages 65 and older.<sup>14</sup> About 5.1 million people in the United States have heart failure.<sup>4</sup>
- For the 60–79-year-old age group, 7.8 percent of men and 4.5 percent of women have **heart failure**. For those age 80 and older, 8.6 percent of men and 11.5 percent of women have heart failure.<sup>14</sup>
- In 2000 and 2010, there were 1 million hospitalizations for **heart failure**, and most of them were for those ages 65 and older.<sup>4</sup>
- **Heart failure** costs the nation an estimated \$32 billion each year, including the cost of health care services, medications to treat heart failure, and missed days of work.<sup>4</sup>

## Hyperlipidemia (High Blood Cholesterol)<sup>4</sup>

- People with **high blood cholesterol** have about twice the risk of **heart disease** as people with lower levels.
- Some 71 million American adults (33.5 percent) have high low-density lipoprotein (LDL), or "**bad,**" **cholesterol**.
- Only 1 out of every 3 adults with **high LDL cholesterol** has the condition under control. Less than half of adults with high LDL cholesterol get treatment.

## Hypertension (High Blood Pressure)<sup>4</sup>

- Some 67 million American adults (31 percent) have **high blood pressure**—that's 1 in every 3 adults. Only about half (47 percent) of people with high blood pressure have their condition under control.
- Women are about as likely as men to develop **high blood pressure** during their lifetimes; however, for people younger than age 45, the condition affects more men than women. For people age 65 and older, high blood pressure affects more women than men.

- More than 348,000 American deaths in 2009 included **high blood pressure** as a primary or contributing cause—that's 1,000 deaths each day.
- **High blood pressure** costs the nation \$47.5 billion each year, including the cost of health care services, medications to treat high blood pressure, and missed days of work.

## Hypothyroidism<sup>15</sup>

- **Hypothyroidism**, a disorder that occurs when the thyroid gland does not make enough thyroid hormone to meet the body's needs, affects about 4.6 percent of the U.S. population age 12 and older. Women are much more likely than men to develop hypothyroidism. The disease is also more common among people older than age 60.

## Ischemic Heart Disease (Coronary Heart Disease)

- **Heart disease** is the leading cause of death for both men and women. About 600,000 people die of heart disease in the United States every year—that's 1 in every 4 deaths.<sup>4</sup>
- **Coronary heart disease (CHD)** is the most common type of heart disease, killing nearly 380,000 people annually.<sup>4</sup> About 80 percent of people who die of CHD are age 65 or older.<sup>14</sup>
- For the 60–79 age group, 21.1 percent of men and 10.6 percent of women have **CHD**. For the age 80 and older age group, 34.6 percent of men and 18.6 percent of women have CHD.<sup>14</sup>
- **Coronary heart disease** alone costs the United States \$108.9 billion each year, including the cost of health care services, medications, and lost productivity.<sup>4</sup>

## Sources:

1. Alzheimer's Association, [www.alz.org](http://www.alz.org)
2. Anemia Organization, [www.anemia.org/resources/education-kit](http://www.anemia.org/resources/education-kit)
3. Arthritis Foundation, [www.arthritis.org](http://www.arthritis.org)
4. U.S. Centers for Disease Control and Prevention, [www.cdc.gov](http://www.cdc.gov)
5. National Eye Institute, [www.nei.nih.gov](http://www.nei.nih.gov)
6. National Council on Aging, [www.ncoa.org](http://www.ncoa.org)
7. Centers for Medicare & Medicaid Services (CMS), *Chronic Conditions Among Medicare Beneficiaries, Chartbook: 2012 Edition*, [www.cms.gov](http://www.cms.gov)
8. National Kidney Foundation, [www.kidney.org](http://www.kidney.org)
9. American Lung Association, [www.lungusa.org](http://www.lungusa.org)
10. National Alliance for Mental Illness, [www.nami.org](http://www.nami.org)
11. Geriatric Mental Health Foundation, [www.gmhfonline.org](http://www.gmhfonline.org)
12. American Diabetes Association, [www.diabetes.org](http://www.diabetes.org)
13. Glaucoma Research Foundation, [www.glaucoma.org](http://www.glaucoma.org)
14. American Heart Association, [www.circres.ahajournals.org](http://www.circres.ahajournals.org)
15. National Institute of Diabetes and Digestive and Kidney Diseases, [www.niddk.nih.gov](http://www.niddk.nih.gov)

## Acquired Hypothyroidism

Product Name	Sponsor	Indication	Development Phase*
BCT303 (liothyronine sustained release)	Intellectual Property Executives (IPE) <i>Kingsport, TN</i>	hypothyroidism	Phase II <a href="http://www.ipeamerica.com">www.ipeamerica.com</a>

## Alzheimer's Disease and Dementia

Product Name	Sponsor	Indication	Development Phase*
AAB-003/PF-05236812 (beta-amyloid protein inhibitor mAb)	Janssen Alzheimer Immunotherapy Research & Development <i>South San Francisco, CA</i> Pfizer <i>New York, NY</i>	Alzheimer's disease	Phase I <a href="http://www.janssenrnd.com">www.janssenrnd.com</a> <a href="http://www.pfizer.com">www.pfizer.com</a>
AC-1204 (glucose stimulant)	Accera <i>Broomfield, CO</i>	mild to moderate Alzheimer's disease	Phase II/III <a href="http://www.accelerapharma.com">www.accelerapharma.com</a>
AD02 vaccine (amyloid-beta protein inhibitor)	Affiris <i>Vienna, Austria</i> GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	Alzheimer's disease	Phase II <a href="http://www.affiris.com">www.affiris.com</a> <a href="http://www.gsk.com">www.gsk.com</a>
ALZ-801 (tramiprosate prodrug)	Alzheon <i>Lexington, MA</i>	Alzheimer's disease	Phase I <a href="http://www.alzheon.com">www.alzheon.com</a>
APH-0703 (protein kinase C stimulant)	Aphios <i>Woburn, MA</i>	Alzheimer's disease	Phase II <a href="http://www.aphios.com">www.aphios.com</a>
ARC029 (nilvadipine)	Archer Pharmaceuticals <i>Sarasota, FL</i>	Alzheimer's disease	Phase I/II <a href="http://www.archerpharma.com">www.archerpharma.com</a>
ARC031 (soluble amyloid reducing/clearing agent)	Archer Pharmaceuticals <i>Sarasota, FL</i>	Alzheimer's disease	Phase I <a href="http://www.archerpharma.com">www.archerpharma.com</a>
AVN 101 (serotonin 5-HT6 receptor antagonist)	Avineuro Pharmaceuticals <i>San Diego, CA</i>	Alzheimer's disease	Phase II <a href="http://www.avineuro.com">www.avineuro.com</a>
AVN 322 (serotonin 6 receptor antagonist)	Avineuro Pharmaceuticals <i>San Diego, CA</i>	Alzheimer's disease	Phase I <a href="http://www.avineuro.com">www.avineuro.com</a>
AVP-923 (dextromethorphan/quinidine fixed-dose combination)	Avanir Pharmaceuticals <i>Aliso Viejo, CA</i>	agitation in Alzheimer's disease	Phase II <a href="http://www.avanir.com">www.avanir.com</a>

\*For more information about a specific medicine or company in the report, please use the website provided.

## Alzheimer's Disease and Dementia

Product Name	Sponsor	Indication	Development Phase*
AZD3293 (beta secretase)	Astex Pharmaceuticals <i>Dublin, CA</i> AstraZeneca <i>Wilmington, DE</i>	Alzheimer's disease	Phase I <a href="http://www.astx.com">www.astx.com</a> <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
BACE inhibitor	Janssen Research & Development <i>Raritan, NJ</i> Shionogi <i>Florham Park, NJ</i>	Alzheimer's disease	Phase I <a href="http://www.janssenrnd.com">www.janssenrnd.com</a> <a href="http://www.shionogi.com">www.shionogi.com</a>
BACE1 protein inhibitor	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> Vitae Pharmaceuticals <i>Fort Washington, PA</i>	Alzheimer's disease	Phase I <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a> <a href="http://www.vitaepharma.com">www.vitaepharma.com</a>
BAN2401 (amyloid beta-protein inhibitor)	Biogen Idec <i>Cambridge, MA</i> Eisai <i>Woodcliff Lake, NJ</i>	early-stage Alzheimer's disease	Phase II <a href="http://www.biogenidec.com">www.biogenidec.com</a> <a href="http://www.eisai.com">www.eisai.com</a>
BIIB037 (human anti-amyloid beta mAb)	Biogen Idec <i>Cambridge, MA</i>	Alzheimer's disease	Phase I <a href="http://www.biogenidec.com">www.biogenidec.com</a>
bisnorcymserine (BNC)	QR Pharma <i>Berwyn, PA</i>	moderate to severe Alzheimer's disease	Phase I <a href="http://www.qrpharma.com">www.qrpharma.com</a>
brexpiprazole (dopamine partial agonist)	Lundbeck <i>Deerfield, IL</i> Otsuka Pharmaceutical <i>Rockville, MD</i>	agitation in Alzheimer's disease (see also depression)	Phase III <a href="http://www.lundbeck.com">www.lundbeck.com</a> <a href="http://www.otsuka.com">www.otsuka.com</a>
bryostatin 1	Neurotrope BioScience <i>Plantation, FL</i>	Alzheimer's disease	Phase II <a href="http://www.neurotrophebioscience.com">www.neurotrophebioscience.com</a>
CAD106 (amyloid beta-protein inhibitor)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	Alzheimer's disease	Phase II <a href="http://www.novartis.com">www.novartis.com</a>
CERE-110 (AAV-NGF)	Sangamo BioSciences <i>Richmond, VA</i>	Alzheimer's disease	Phase II <a href="http://www.sangamo.com">www.sangamo.com</a>
CHF-5074 (amyloid beta-protein inhibitor)	CereSpir <i>New York, NY</i>	Alzheimer's disease	Phase II
CPC-201	Chase Pharmaceuticals <i>Washington, DC</i>	Alzheimer's disease	Phase I <a href="http://www.chasepharmaceuticals.com">www.chasepharmaceuticals.com</a>
crenezumab (anti-amyloid-beta mAb)	Genentech <i>South San Francisco, CA</i>	Alzheimer's disease	Phase II <a href="http://www.gene.com">www.gene.com</a>

## Alzheimer's Disease and Dementia

Product Name	Sponsor	Indication	Development Phase*
donepezil/memantine extended release (fixed-dose combination)	Adamas Pharmaceuticals <i>Emeryville, CA</i> Forest Laboratories <i>New York, NY</i>	moderate to severe Alzheimer's disease	application submitted <a href="http://www.adamaspharma.com">www.adamaspharma.com</a> <a href="http://www.frx.com">www.frx.com</a>
E2609 (BACE1 protein inhibitor)	Biogen Idec <i>Cambridge, MA</i> Eisai <i>Woodcliff Lake, NJ</i>	Alzheimer's disease	Phase I <a href="http://www.biogenidec.com">www.biogenidec.com</a> <a href="http://www.eisai.com">www.eisai.com</a>
ELND005 (amyloid beta-protein inhibitor)	Transition Therapeutics <i>Toronto, Canada</i>	agitation and aggression in Alzheimer's disease (Fast Track)	Phase II <a href="http://www.transitiontherapeutics.com">www.transitiontherapeutics.com</a>
encenicline (alpha7 nicotinic acetylcholine receptor agonist)	FORUM Pharmaceuticals <i>Watertown, MA</i>	Alzheimer's disease	Phase III <a href="http://www.forumpharma.com">www.forumpharma.com</a>
FRM-0962 (gamma secretase modulator)	FORUM Pharmaceuticals <i>Watertown, MA</i>	Alzheimer's disease	Phase II <a href="http://www.forumpharma.com">www.forumpharma.com</a>
gantenerumab (RG1450)	Roche <i>Nutley, NJ</i>	early-stage Alzheimer's disease	Phase III <a href="http://www.roche.com">www.roche.com</a>
GSK2647544 (Lp-PLA2 inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	Alzheimer's disease	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
HT-0712 (PDE4 inhibitor)	Dart NeuroScience <i>San Diego, CA</i>	age-associated memory impairment	Phase II <a href="http://www.dartneuroscience.com">www.dartneuroscience.com</a>
immune globulin	Grifols <i>Barcelona, Spain</i>	Alzheimer's disease	Phase II/III <a href="http://www.grifols.com">www.grifols.com</a>
JNJ-54861911	Janssen Research & Development <i>Raritan, NJ</i>	Alzheimer's disease	Phase I <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
KU-046 (amyloid beta-protein modulator)	Kareus Therapeutics <i>La Chaux-de-Fonds, Switzerland</i>	Alzheimer's disease	Phase I <a href="http://www.kareustherapeutics.com">www.kareustherapeutics.com</a>
Lu AE58054 (5-HT6 receptor antagonist)	Lundbeck <i>Deerfield, IL</i> Otsuka America Pharmaceutical <i>Rockville, MD</i>	Alzheimer's disease (cognition)	Phase III <a href="http://www.lundbeck.com">www.lundbeck.com</a> <a href="http://www.otsuka.com">www.otsuka.com</a>
LY3002813 (N3pG-AB mAb)	Eli Lilly <i>Indianapolis, IN</i>	Alzheimer's disease	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
MEDI1841	AstraZeneca <i>Wilmington, DE</i>	mild-moderate Alzheimer's disease	Phase I <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>

## Alzheimer's Disease and Dementia

Product Name	Sponsor	Indication	Development Phase*
MK-7622	Merck <i>Whitehouse Station, NJ</i>	Alzheimer's disease	Phase II <a href="http://www.merck.com">www.merck.com</a>
MK-8931 (BACE1 protein inhibitor)	Merck <i>Whitehouse Station, NJ</i>	Alzheimer's disease	Phase III <a href="http://www.merck.com">www.merck.com</a>
MSDC-0160 (mTOT modulator)	Metabolic Solutions Development Company <i>Kalamazoo, MI</i>	Alzheimer's disease	Phase II <a href="http://www.msdrx.com">www.msdrx.com</a>
NAV4694 (fluorine-18 labeled precision radiopharmaceutical)	Navidea Biopharmaceuticals <i>Dublin, OH</i>	Alzheimer's disease (diagnosis)	Phase III <a href="http://www.navidea.com">www.navidea.com</a>
NAV5001 (123I-labelled imaging agent)	Navidea Biopharmaceuticals <i>Dublin, OH</i>	dementia with Lewy bodies (diagnosis)	Phase II <a href="http://www.navidea.com">www.navidea.com</a>
NIC5-15 (amyloid precursor protein secretase inhibitor)	Humanetics <i>Minneapolis, MN</i>	Alzheimer's disease	Phase II <a href="http://www.humaneticscorp.com">www.humaneticscorp.com</a>
<b>Pepticle</b> <sup>™</sup> DP-74 peptide nasal delivery	ProteoTech <i>Kirkland, WA</i>	Alzheimer's disease	Phase I <a href="http://www.proteotech.com">www.proteotech.com</a>
PF-05212377 (SAM-760)	Pfizer <i>New York, NY</i>	Alzheimer's disease	Phase II <a href="http://www.pfizer.com">www.pfizer.com</a>
pioglitazone (low dose)	Takeda Pharmaceuticals <i>Deerfield, IL</i> Zinfandel Pharmaceuticals <i>Chapel Hill, NC</i>	prevention of Alzheimer's disease in people with genetic risk variations	Phase III <a href="http://www.takeda.com">www.takeda.com</a>
pioglitazone companion diagnostic (AD4833/TOMM40)	Takeda Pharmaceuticals <i>Deerfield, IL</i> Zinfandel Pharmaceuticals <i>Chapel Hill, NC</i>	Alzheimer's disease (diagnosis)	Phase III <a href="http://www.takeda.com">www.takeda.com</a>
<b>Posiphen</b> <sup>®</sup> R-phenserine	QR Pharma <i>Berwyn, PA</i>	early Alzheimer's disease	Phase II <a href="http://www.qrpharma.com">www.qrpharma.com</a>
PTI-80 (amyloid-beta-protein/tau protein inhibitor)	ProteoTech <i>Kirkland, WA</i>	Alzheimer's disease	Phase I completed <a href="http://www.proteotech.com">www.proteotech.com</a>
RG1577 (MAO-B inhibitor)	Roche <i>Nutley, NJ</i>	Alzheimer's disease	Phase II <a href="http://www.roche.com">www.roche.com</a>
rilapladib (Lp-PLA2 inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	Alzheimer's disease	Phase II <a href="http://www.gsk.com">www.gsk.com</a>

## Alzheimer's Disease and Dementia

Product Name	Sponsor	Indication	Development Phase*
RVX-208 (BET protein inhibitor)	Resverlogix <i>Calgary, Canada</i>	Alzheimer's disease	Phase I completed <a href="http://www.resverlogix.com">www.resverlogix.com</a>
SAR228810 (anti-protofibrillar AB mAb)	Sanofi US <i>Bridgewater, NJ</i>	Alzheimer's disease	Phase I <a href="http://www.sanofi.com">www.sanofi.com</a>
sGC-1061 (nomethiazole)	sGC Pharma <i>Wellesley, MA</i>	Alzheimer's disease	Phase I <a href="http://www.sgcpharma.com">www.sgcpharma.com</a>
solanezumab (amyloid-beta protein inhibitor)	Eli Lilly <i>Indianapolis, IN</i>	mild Alzheimer's disease	Phase III <a href="http://www.lilly.com">www.lilly.com</a>
ST101	Sonexa Therapeutics <i>San Diego, CA</i>	Alzheimer's disease	Phase II completed <a href="http://www.sonexa.com">www.sonexa.com</a>
SUVN-502 (5-HT6 receptor antagonist)	Suvun Life Sciences <i>Hyderabad, India</i>	Alzheimer's disease	Phase I <a href="http://www.suven.com">www.suven.com</a>
SYN120 (dual 5-HT6 and 2A receptor antagonist)	Biotie Therapies <i>South San Francisco, CA</i>	Alzheimer's disease	Phase I completed <a href="http://www.biotie.com">www.biotie.com</a>
T3D-959 (dual PPAR agonist)	T3D Therapeutics <i>Rsch. Triangle Park, NC</i>	Alzheimer's disease	Phase I completed <a href="http://www.t3dtherapeutics.com">www.t3dtherapeutics.com</a>
T-817MA (amyloid beta-protein inhibitor)	Toyama Chemical <i>Tokyo, Japan</i>	Alzheimer's disease	Phase II <a href="http://www.toyama-chemical.co.jp">www.toyama-chemical.co.jp</a>
tau imaging agent (18F-AV-1451)	Avid Radiopharmaceuticals <i>Philadelphia, PA</i> Eli Lilly <i>Indianapolis, IN</i>	Alzheimer's disease (diagnosis)	Phase II <a href="http://www.lilly.com">www.lilly.com</a>
TC-1734 (ispronicline)	Targacept <i>Winston-Salem, NC</i>	Alzheimer's disease	Phase II <a href="http://www.targacept.com">www.targacept.com</a>
TPI-287 (next generation taxane)	Cortice Biosciences <i>New York, NY</i>	Alzheimer's disease	Phase II <a href="http://www.corticebio.com">www.corticebio.com</a>
TRx0237 (tau aggregation inhibitor)	TauRx Pharmaceuticals <i>Singapore</i>	Alzheimer's disease, frontotemporal dementia	Phase III <a href="http://www.taurx.com">www.taurx.com</a>
TTP488 (RAGE inhibitor)	Transtech Pharma <i>High Point, NC</i>	Alzheimer's disease (Fast Track)	Phase II <a href="http://www.ttpharma.com">www.ttpharma.com</a>
TTP4000 (IgG and RAGE inhibitor)	Transtech Pharma <i>High Point, NC</i>	Alzheimer's disease	Phase I <a href="http://www.ttpharma.com">www.ttpharma.com</a>
UB-311 (liquid intramuscular amyloid beta protein inhibitor vaccine)	United Biomedical <i>Hauppauge, NY</i>	mild to moderate Alzheimer's disease	Phase II <a href="http://www.unitedbiomedical.com">www.unitedbiomedical.com</a>

## Anemia

Product Name	Sponsor	Indication	Development Phase*
ACE-536 (TGF-beta superfamily protein inhibitor)	Acceleron Pharma <i>Cambridge, MA</i> Celgene <i>Summit, NJ</i>	anemia in patients with myelodysplastic syndrome	Phase II <a href="http://www.acceleronpharma.com">www.acceleronpharma.com</a> <a href="http://www.celgene.com">www.celgene.com</a>
Aes-103 ORPHAN DRUG	AesRx <i>Newton, MA</i>	sickle cell anemia	Phase I/II <a href="http://www.aesrx.com">www.aesrx.com</a>
AGS-348 (PK modulator)	Agios Pharmaceuticals <i>Cambridge, MA</i>	hereditary haematologic anemia	Phase I <a href="http://www.agios.com">www.agios.com</a>
AKB-6548 (HIF-PH inhibitor)	Akebia Therapeutics <i>Cambridge, MA</i>	anemia associated with chronic kidney disease	Phase II <a href="http://www.akebia.com">www.akebia.com</a>
<b>Epodure™</b> erythropoietin gene therapy	Medgenics <i>Wayne, PA</i>	anemia associated with chronic kidney disease	Phase II <a href="http://www.medgenics.com">www.medgenics.com</a>
epoetin alfa biosimilar	Sandoz <i>Princeton, NJ</i>	anemia associated with chronic kidney disease	Phase III <a href="http://www.us.sandoz.com">www.us.sandoz.com</a>
epoetin zeta	Hospira <i>Lake Forest, IL</i>	anemia in chronic renal failure	Phase III <a href="http://www.hospira.com">www.hospira.com</a>
glutamine ORPHAN DRUG	Emmaus Medical <i>Torrance, CA</i>	sickle cell anemia (Fast Track)	Phase III <a href="http://www.emmausmedical.com">www.emmausmedical.com</a>
GSK1278863 (prolyl hydroxylase inhibitor)	GlaxoSmithKline <i>Research Triangle Park, NC</i>	anemia associated with chronic renal disease and perioperative risk reduction	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
hepcidin mAb	Eli Lilly <i>Indianapolis, IN</i>	anemia	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
HM10760A (erythropoietin long acting)	Hanmi Pharmaceutical <i>Seoul, South Korea</i>	anemia	Phase I completed <a href="http://www.hanmipharm.com">www.hanmipharm.com</a>
iron isomaltoside 1000	Pharmacosmos <i>Holbaek, Denmark</i>	iron deficiency anemia	Phase III <a href="http://www.pharmacosmos.com">www.pharmacosmos.com</a>
JTZ- 951 (HIF-PHD inhibitor)	Akros Pharma <i>Princeton, NJ</i> Japan Tobacco <i>Tokyo, Japan</i>	anemia associated with chronic kidney disease	Phase I <a href="http://www.akrospharma.com">www.akrospharma.com</a>
KRX-0502 (ferric citrate)	Keryx Biopharmaceuticals <i>New York, NY</i>	hyperphosphatemia associated with chronic kidney disease	application submitted <a href="http://www.keryx.com">www.keryx.com</a>
		iron deficiency anemia associated with chronic kidney disease	Phase II <a href="http://www.keryx.com">www.keryx.com</a>

## Anemia

Product Name	Sponsor	Indication	Development Phase*
<b>LentiGlobin®</b> b-globin gene therapy	bluebird bio <i>Cambridge, MA</i>	beta-thalassemia	Phase I/II <a href="http://www.bluebirdbio.com">www.bluebirdbio.com</a>
LY2928057 (ferroportin mAb)	Eli Lilly <i>Indianapolis, IN</i>	anemia	Phase II <a href="http://www.lilly.com">www.lilly.com</a>
molidustat (HIF-PH inhibitor)	Bayer HealthCare Pharmaceuticals <i>Whippany, NJ</i>	anemia associated with chronic renal failure	Phase II <a href="http://www.bayerpharm.com">www.bayerpharm.com</a>
MST-188 ORPHAN DRUG	Mast Therapeutics <i>San Diego, CA</i>	sickle cell anemia	Phase III <a href="http://www.masttherapeutics.com">www.masttherapeutics.com</a>
<b>NiCord®</b> stem cell therapy	Gamida Cell <i>Jerusalem, Israel</i>	sickle cell anemia, thalassemia	Phase I/II <a href="http://www.gamida-cell.com">www.gamida-cell.com</a>
NKTT-120	NKT Therapeutics <i>Waltham, MA</i>	sickle cell anemia	Phase I <a href="http://www.nktrx.com">www.nktrx.com</a>
<b>Promacta®</b> eltrombopag	GlaxoSmithKline <i>Research Triangle Park, NC</i>	aplastic anemia	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
rivipansel (Pan-selectin antagonist)	Pfizer <i>New York, NY</i>	vaso-occlusive crisis associated with sickle cell anemia	Phase II <a href="http://www.pfizer.com">www.pfizer.com</a>
roxadustat (FG-4592)	AstraZeneca <i>Wilmington, DE</i> FibroGen <i>San Francisco, CA</i>	anemia associated with chronic kidney disease	Phase III <a href="http://www.astrazeneca.com">www.astrazeneca.com</a> <a href="http://www.fibrogen.com">www.fibrogen.com</a>
SeIG1 (Pan selectin inhibitor) ORPHAN DRUG	Selexys Pharmaceuticals <i>Oklahoma City, OK</i>	sickle cell anemia	Phase I/II <a href="http://www.selexys.com">www.selexys.com</a>
sotatercept	Acceleron Pharma <i>Cambridge, MA</i> Celgene <i>Summit, NJ</i>	chemotherapy-induced anemia	Phase II/III <a href="http://www.acceleronpharma.com">www.acceleronpharma.com</a> <a href="http://www.celgene.com">www.celgene.com</a>
		anemia associated with end-stage renal disease	Phase II <a href="http://www.acceleronpharma.com">www.acceleronpharma.com</a> <a href="http://www.celgene.com">www.celgene.com</a>
ST10 (ferric maltol)	Shield Therapeutics <i>London, United Kingdom</i>	iron deficiency anemia	Phase III <a href="http://www.shieldtherapeutics.com">www.shieldtherapeutics.com</a>
<b>Triferic™</b> soluble ferric pyrophosphate	Rockwell Medical Technologies <i>Wixom, MI</i>	iron deficiency anemia	application submitted <a href="http://www.rockwellmed.com">www.rockwellmed.com</a>

## Arthritis

Product Name	Sponsor	Indication	Development Phase*
ABP 501 (adalimumab biosimilar)	Amgen <i>Thousand Oaks, CA</i>	rheumatoid arthritis	Phase III <a href="http://www.amgen.com">www.amgen.com</a>
ABT-122 (dual IL-17/TNF inhibitor)	AbbVie <i>North Chicago, IL</i>	rheumatoid arthritis	Phase I <a href="http://www.abbvie.com">www.abbvie.com</a>
ABT-494 (JAK1/JAK2/JAK3 inhibitor)	AbbVie <i>North Chicago, IL</i>	rheumatoid arthritis	Phase II <a href="http://www.abbvie.com">www.abbvie.com</a>
ABT-981 (IL-1 alpha/IL-1 beta inhibitor)	AbbVie <i>North Chicago, IL</i>	osteoarthritis of the knee	Phase II <a href="http://www.abbvie.com">www.abbvie.com</a>
ALX-0061 (IL-6 receptor modulator)	AbbVie <i>North Chicago, IL</i> Ablynx <i>Ghent, Belgium</i>	rheumatoid arthritis	Phase I/II <a href="http://www.abbvie.com">www.abbvie.com</a> <a href="http://www.ablynx.com">www.ablynx.com</a>
<b>Ampion™</b>	Ampio Pharmaceuticals <i>Greenwood Village, CO</i>	osteoarthritis of the knee	Phase III <a href="http://www.ampiopharma.com">www.ampiopharma.com</a>
ASP015K (JAK inhibitor)	Astellas Pharma <i>Tokyo, Japan</i> Janssen Research & Development <i>Raritan, NJ</i>	rheumatoid arthritis	Phase II <a href="http://www.astellas.com">www.astellas.com</a> <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
baricitinib (JAK1/JAK2 inhibitor)	Eli Lilly <i>Indianapolis, IN</i> Incyte <i>Wilmington, DE</i>	rheumatoid arthritis (see also chronic kidney disease)	Phase III <a href="http://www.lilly.com">www.lilly.com</a> <a href="http://www.incyte.com">www.incyte.com</a>
BI 655064 (CD40 antigen inhibitor)	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	rheumatoid arthritis	Phase I <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>
BI 695500 (rituximab biosimilar)	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	rheumatoid arthritis	Phase III <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>
BI 695501 (adalimumab biosimilar)	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	rheumatoid arthritis	Phase I <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>
BT-061 (tregalizumab)	AbbVie <i>North Chicago, IL</i>	rheumatoid arthritis	Phase II <a href="http://www.abbvie.com">www.abbvie.com</a>
Btk inhibitor	Pharmacyclics <i>Sunnyvale, CA</i>	rheumatoid arthritis	Phase I <a href="http://www.pharmacyclics.com">www.pharmacyclics.com</a>
cadherin-11 (SDP051)	Adheron Therapeutics <i>Berkeley, CA</i>	rheumatoid arthritis	Phase I completed <a href="http://www.adherontherapeutics.com">www.adherontherapeutics.com</a>

## Arthritis

Product Name	Sponsor	Indication	Development Phase
CC-292 (Btk inhibitor)	Celgene <i>Summit, NJ</i>	rheumatoid arthritis	Phase II <a href="http://www.celgene.com">www.celgene.com</a>
CCX354 (CCR1 chemokine receptor)	ChemoCentryx <i>Mountain View, CA</i>	rheumatoid arthritis	Phase I <a href="http://www.chemocentryx.com">www.chemocentryx.com</a>
CEP-41750 (stem cell therapy)	Mesoblast <i>New York, NY</i>	refractory rheumatoid arthritis	Phase II <a href="http://www.mesoblast.com">www.mesoblast.com</a>
CF101 (adenosine A3 receptor agonist)	Can-Fite Pharma <i>Waltham, MA</i>	rheumatoid arthritis (see also glaucoma)	Phase II <a href="http://www.canfite.com">www.canfite.com</a>
CFZ533	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	rheumatoid arthritis	Phase I <a href="http://www.novartis.com">www.novartis.com</a>
clazakizumab (BMS-945429)	Bristol-Myers Squibb <i>Princeton, NJ</i>	rheumatoid arthritis	Phase II <a href="http://www.bms.com">www.bms.com</a>
CNTO 6785 (IL-17A modulator)	Janssen Research & Development <i>Raritan, NJ</i>	rheumatoid arthritis (see also COPD)	Phase II <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
<b>Dekavil</b> F8 antibody-IL10	Pfizer <i>New York, NY</i>	rheumatoid arthritis	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
EP4-R antagonist	Eli Lilly <i>Indianapolis, IN</i>	osteoarthritis pain	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
FPA008 (IL-34/CSF1 inhibitor)	Five Prime Therapeutics <i>South San Francisco, CA</i>	rheumatoid arthritis	Phase I <a href="http://www.fiveprime.com">www.fiveprime.com</a>
gevokizumab	XOMA <i>Berkeley, CA</i>	erosive osteoarthritis of the hand	Phase II <a href="http://www.xoma.com">www.xoma.com</a>
GLPG0634 (JAK1 inhibitor)	AbbVie <i>North Chicago, IL</i> Galapagos <i>Mechelen, Belgium</i>	rheumatoid arthritis	Phase II <a href="http://www.abbvie.com">www.abbvie.com</a> <a href="http://www.glp.com">www.glp.com</a>
GSK311739 (macrophage targeted histone deacetylase inhibitor)	GlaxoSmithKline <i>Research Triangle Park, NC</i>	rheumatoid arthritis	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
GSK3196165 (MOR103) (granulocyte macrophage colony-stimulating factor mAb)	GlaxoSmithKline <i>Research Triangle Park, NC</i>	rheumatoid arthritis	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
guselkumab	Janssen Research & Development <i>Raritan, NJ</i>	rheumatoid arthritis	Phase II <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>

## Arthritis

Product Name	Sponsor	Indication	Development Phase
ibuprofenamine (X0002)	Techfields Pharma <i>Jiangsu, China</i>	osteoarthritis	Phase II <a href="http://www.tfpharma.com">www.tfpharma.com</a>
INCB47986 (JAK1 inhibitor)	Incyte <i>Wilmington, DE</i>	rheumatoid arthritis	Phase I <a href="http://www.incyte.com">www.incyte.com</a>
IPI-145 (dual PI3K inhibitor)	Infinity Pharmaceuticals <i>Cambridge, MA</i>	rheumatoid arthritis	Phase II <a href="http://www.infi.com">www.infi.com</a>
JNJ-38518168 (histamine H4 receptor antagonist)	Janssen Research & Development <i>Raritan, NJ</i>	active rheumatoid arthritis	Phase II <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
JNJ-40346527 (FMS inhibitor)	Janssen Research & Development <i>Raritan, NJ</i>	active rheumatoid arthritis	Phase II <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
KD025 (ROCK2 inhibitor)	Kadmon <i>New York, NY</i>	rheumatoid arthritis	Phase I <a href="http://www.kadmon.com">www.kadmon.com</a>
(L/D)-aminopterin	Syntrix Biosystems <i>Auburn, WA</i>	rheumatoid arthritis	Phase II <a href="http://www.syntrixbio.com">www.syntrixbio.com</a>
LY3090106	Eli Lilly <i>Indianapolis, IN</i>	rheumatoid arthritis	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
mavrilimumab (anti-GM-CSFR mAb)	MedImmune <i>Gaithersburg, MD</i>	rheumatoid arthritis	Phase II <a href="http://www.medimmune.com">www.medimmune.com</a>
mesenchymal stem cell therapy for cartilage repair	Medipost <i>Seoul, South Korea</i>	osteoarthritis	Phase I/II <a href="http://www.medi-post.com">www.medi-post.com</a>
MK-8808 (rituximab biosimilar)	Merck <i>Whitehouse Station, NJ</i>	rheumatoid arthritis	Phase I completed <a href="http://www.merck.com">www.merck.com</a>
MORAb-022 (IgG1 mAb)	Eisai <i>Woodcliff Lake, NJ</i>	rheumatoid arthritis	Phase I <a href="http://www.eisai.com">www.eisai.com</a>
NN8210 (anti-C5aR-215)	Novo Nordisk <i>Plainsboro, NJ</i>	rheumatoid arthritis	Phase I <a href="http://www.novonordisk.com">www.novonordisk.com</a>
NN8226 (anti-IL20 antibody)	Novo Nordisk <i>Plainsboro, NJ</i>	rheumatoid arthritis	Phase II <a href="http://www.novonordisk.com">www.novonordisk.com</a>
<b>Otezla®</b> apremilast	Celgene <i>Summit, NJ</i>	rheumatoid arthritis	Phase II <a href="http://www.celgene.com">www.celgene.com</a>
PF-04171327 (selective glucocorticoid receptor modulator)	Pfizer <i>New York, NY</i>	rheumatoid arthritis	Phase II <a href="http://www.pfizer.com">www.pfizer.com</a>

## Arthritis

Product Name	Sponsor	Indication	Development Phase
PF-05280586 (rituximab biosimilar)	Pfizer <i>New York, NY</i>	rheumatoid arthritis	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
PF-06410293 (adalimumab biosimilar)	Pfizer <i>New York, NY</i>	rheumatoid arthritis	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
PF-06438179 (infliximab biosimilar)	Pfizer <i>New York, NY</i>	rheumatoid arthritis	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
PRTX-100 (staphylococcal protein A)	Protalex <i>Florham Park, NJ</i>	active rheumatoid arthritis	Phase I <a href="http://www.protalex.com">www.protalex.com</a>
QAL964	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	rheumatoid arthritis	Phase II <a href="http://www.novartis.com">www.novartis.com</a>
<b>Rasuvo™</b> methotrexate subcutaneous auto-injection	Medac Pharma <i>Chicago, IL</i>	rheumatoid arthritis	application submitted <a href="http://www.medacpharma.com">www.medacpharma.com</a>
<b>Ravax™</b> rheumatoid arthritis vaccine	Immune Response BioPharma <i>Atlantic City, NJ</i>	rheumatoid arthritis	Phase III <a href="http://www.immuneresponsebiopharma.com">www.immuneresponsebiopharma.com</a>
SAN-300 (VLA-1 mAb)	Salix Pharmaceuticals <i>Raleigh, NC</i>	rheumatoid arthritis	Phase II <a href="http://www.salix.com">www.salix.com</a>
sarilumab (anti-IL-6R mAb)	Regeneron Pharmaceuticals <i>Tarrytown, NY</i> Sanofi US <i>Bridgewater, NJ</i>	rheumatoid arthritis	Phase III <a href="http://www.regeneron.com">www.regeneron.com</a> <a href="http://www.sanofi.com">www.sanofi.com</a>
secukinumab (IL-17 inhibitor)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	rheumatoid arthritis (see also diabetes)	Phase III <a href="http://www.novartis.com">www.novartis.com</a>
sirukumab	Janssen Research & Development <i>Raritan, NJ</i>	rheumatoid arthritis	Phase III <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
SM-04690 (Wnt pathway modulator)	Samumed <i>San Diego, CA</i>	osteoarthritis of the knee	Phase I <a href="http://www.samumed.com">www.samumed.com</a>
sprifermin (FGF-18)	EMD Serono <i>Rockland, MA</i>	osteoarthritis	Phase II <a href="http://www.emdserono.com">www.emdserono.com</a>
TG-C (cell therapy)	TissueGene <i>Rockville, MD</i>	osteoarthritis of the knee	Phase II <a href="http://www.tissuegene.com">www.tissuegene.com</a>
TPX-100 (MEPE-derived 23-amino acid peptide)	OrthoTrophix <i>Oakland, CA</i>	osteoarthritis of the knee	Phase II <a href="http://www.orthotrophix.com">www.orthotrophix.com</a>

## Arthritis

Product Name	Sponsor	Indication	Development Phase
VX-509 (JAK3 inhibitor)	Vertex Pharmaceuticals <i>Boston, MA</i>	rheumatoid arthritis	Phase II <a href="http://www.vrtx.com">www.vrtx.com</a>
<b>XmAb®5871</b> anti-CD19 mAb	Xencor <i>Monrovia, CA</i>	moderate to severe rheumatoid arthritis	Phase II <a href="http://www.xencor.com">www.xencor.com</a>

## Chronic Kidney Disease

Product Name	Sponsor	Indication	Development Phase
atrasentan	AbbVie <i>North Chicago, IL</i>	diabetic nephropathy	Phase III <a href="http://www.abbvie.com">www.abbvie.com</a>
AZD1772//RDX5791 (NHE3 inhibitor)	Ardelyx <i>Fremont, CA</i> AstraZeneca <i>Wilmington, DE</i>	management of fluid retention in chronic kidney disease and type 2 diabetes (see also heart disease)	Phase II <a href="http://www.ardelyx.com">www.ardelyx.com</a> <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
baricitinib (JAK1/JAK2 inhibitor)	Eli Lilly <i>Indianapolis, IN</i> Incyte <i>Wilmington, DE</i>	diabetic nephropathy (see also arthritis)	Phase II <a href="http://www.lilly.com">www.lilly.com</a> <a href="http://www.incyte.com">www.incyte.com</a>
BIIB023 (anti-TWEAK mAb)	Biogen Idec <i>Cambridge, MA</i>	lupus nephritis	Phase II <a href="http://www.biogenidec.com">www.biogenidec.com</a>
bosutinib (Abl and src-family kinase inhibitor)	Pfizer <i>New York, NY</i>	autosomal dominant polycystic kidney disease	Phase II <a href="http://www.pfizer.com">www.pfizer.com</a>
CCR2/CCR5 chemokine receptor antagonist (BMS-813160)	Bristol-Myers Squibb <i>Princeton, NJ</i>	diabetic nephropathy	Phase II <a href="http://www.bms.com">www.bms.com</a>
CCX140 (CCR2 receptor antagonist)	ChemoCentryx <i>Mountain View, CA</i>	diabetic nephropathy	Phase II <a href="http://www.chemocentryx.com">www.chemocentryx.com</a>
CCX872 (CCR2 receptor antagonist)	ChemoCentryx <i>Mountain View, CA</i>	diabetic nephropathy	Phase I <a href="http://www.chemocentryx.com">www.chemocentryx.com</a>
CLP-1004 (potassium channel modulator)	Sorbent Therapeutics <i>Sunnyvale, CA</i>	removal of excess fluid associated with chronic kidney disease	Phase I <a href="http://www.sorbent.com">www.sorbent.com</a>
CTP-499	Concert Pharmaceuticals <i>Lexington, MA</i>	diabetic nephropathy	Phase II <a href="http://www.concertpharma.com">www.concertpharma.com</a>

## Chronic Kidney Disease

Product Name	Sponsor	Indication	Development Phase
finerenone (MR antagonist)	Bayer HealthCare Pharmaceuticals <i>Whippany, NJ</i>	diabetic nephropathy (see also heart disease)	Phase II <a href="http://www.bayerpharma.com">www.bayerpharma.com</a>
GCS-100 (galectin inhibitor)	La Jolla Pharmaceutical <i>San Diego, CA</i>	chronic kidney disease	Phase II <a href="http://www.ljpc.com">www.ljpc.com</a>
GKT137831	Genkyotex Innovation <i>Geneva, Switzerland</i>	diabetic nephropathy	Phase II <a href="http://www.genkyotex.com">www.genkyotex.com</a>
GS-4977 (ASK-1 inhibitor)	Gilead Sciences <i>Foster City, CA</i>	diabetic nephropathy	Phase I <a href="http://www.gilead.com">www.gilead.com</a>
<b>H.P. Acthar® Gel</b> repository corticotropin injection	Questcor Pharmaceuticals <i>Anaheim Hills, CA</i>	diabetic nephropathy	Phase II <a href="http://www.questcor.com">www.questcor.com</a>
<b>Invokana®</b> canagliflozin	Janssen Research & Development <i>Raritan, NJ</i>	diabetic neuropathy	Phase III <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
KD020 (MTP inhibitor)	Kadmon Pharmaceuticals <i>New York, NY</i>	polycystic kidney disease	Phase I/II <a href="http://www.kadmon.com">www.kadmon.com</a>
laquinimod	Teva Pharmaceutical <i>North Wales, PA</i>	lupus nephritis	Phase II <a href="http://www.tevapharm.com">www.tevapharm.com</a>
LCZ696 (NEP inhibitor and angiotensin type 1 receptor blocker)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	chronic kidney disease (see also heart disease)	Phase III <a href="http://www.novartis.com">www.novartis.com</a>
LHW090	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	chronic renal insufficiency	Phase I <a href="http://www.novartis.com">www.novartis.com</a>
MT-3995 (selective aldosterone receptor antagonist)	Mitsubishi Tanabe Pharma <i>Osaka, Japan</i>	diabetic nephropathy	Phase I <a href="http://www.mt-pharma.co.jp">www.mt-pharma.co.jp</a>
NCE therapeutic	Eli Lilly <i>Indianapolis, IN</i>	chronic kidney disease	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
<b>Neo-Kidney Augment™</b> autologous cultured kidney tissue cells	Tengion <i>Winston-Salem, NC</i>	chronic kidney disease in patients with type 2 diabetes	Phase I <a href="http://www.tengion.com">www.tengion.com</a>
PF-00489791 (PDES inhibitor)	Pfizer <i>New York, NY</i>	diabetic nephropathy	Phase II <a href="http://www.pfizer.com">www.pfizer.com</a>
PF-04634817 (CCR2/5 antagonist)	Pfizer <i>New York, NY</i>	diabetic nephropathy	Phase II <a href="http://www.pfizer.com">www.pfizer.com</a>

## Chronic Kidney Disease

Product Name	Sponsor	Indication	Development Phase
pyridoxamine	NephroGenex <i>Research Triangle Park, NC</i>	diabetic nephropathy (Fast Track)	Phase II <a href="http://www.nephrogenex.com">www.nephrogenex.com</a>
RG7641	Roche <i>Nutley, NJ</i>	kidney disease	Phase I <a href="http://www.roche.com">www.roche.com</a>
TGF- $\alpha$ .epiregulin mAb (LY3016859)	Eli Lilly <i>Indianapolis, IN</i>	chronic kidney disease	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
tolvaptan	Otsuka Pharmaceutical <i>Rockville, MD</i>	autosomal dominant polycystic kidney disease (Fast Track)	application submitted <a href="http://www.otsuka.com">www.otsuka.com</a>
<b>Tradjenta</b> <sup>®</sup> linagliptin	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> Eli Lilly <i>Indianapolis, IN</i>	diabetic nephropathy	Phase III <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a> <a href="http://www.lilly.com">www.lilly.com</a>

## Chronic Obstructive Pulmonary Disease (COPD)

Product Name	Sponsor	Indication	Development Phase
aclidinium/formoterol inhalation	Almirall <i>Barcelona, Spain</i> Forest Laboratories <i>New York, NY</i>	chronic obstructive pulmonary disease (COPD)	Phase III <a href="http://www.frx.com">www.frx.com</a>
<b>AdipoCell</b> <sup>™</sup> adipose-derived autologous stem cell therapy	Bioheart <i>Sunrise, FL</i>	COPD (see also heart disease)	Phase II <a href="http://www.bioheartinc.com">www.bioheartinc.com</a>
ARD-3150 (liposomal ciprofloxacin) ORPHAN DRUG	Aradigm <i>Hayward, CA</i>	non-cystic fibrosis bronchiectasis	Phase III <a href="http://www.aradigm.com">www.aradigm.com</a>
AZD2115 (MABA)	AstraZeneca <i>Wilmington, DE</i>	COPD	Phase II <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
AZD4721 (CXCR2 antagonist)	AstraZeneca <i>Wilmington, DE</i>	COPD	Phase I <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
AZD7624 (inhaled P38 inhibitor)	AstraZeneca <i>Wilmington, DE</i>	COPD	Phase I <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>

## Chronic Obstructive Pulmonary Disease (COPD)

Product Name	Sponsor	Indication	Development Phase
BAY 85-8501 (neutrophil elastase inhibitor)	Bayer HealthCare Pharmaceuticals <i>Whippany, NJ</i>	bronchiectasis	Phase II <a href="http://www.bayerpharma.com">www.bayerpharma.com</a>
BCT197	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	COPD	Phase II <a href="http://www.novartis.com">www.novartis.com</a>
benralizumab (anti-IL-5R mAb)	MedImmune <i>Gaithersburg, MD</i>	COPD	Phase II <a href="http://www.medimmune.com">www.medimmune.com</a>
<b>Bronchitol</b> mannitol inhalation ORPHAN DRUG	Pharmaxis <i>Frenchs Forest, Australia</i>	bronchiectasis	Phase III <a href="http://www.pharmaxis.com.au">www.pharmaxis.com.au</a>
ciprofloxacin dry powder for inhalation ORPHAN DRUG	Bayer HealthCare Pharmaceuticals <i>Whippany, NJ</i>	non-cystic fibrosis bronchiectasis	Phase III <a href="http://www.bayerpharma.com">www.bayerpharma.com</a>
CNT0 6785 (IL-17A modulator)	Janssen Research & Development <i>Raritan, NJ</i>	COPD (see also arthritis)	Phase II <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
danirixin (CXCR2 chemokine receptor antagonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
erdosteine	Alitair Pharmaceuticals <i>Morristown, NJ</i>	bronchitis	Phase II <a href="http://www.alitair.com">www.alitair.com</a>
fluticasone furoate/vilanterol/ umeclidinium	GlaxoSmithKline <i>Research Triangle Park, NC</i> Theravance Biopharma U.S. <i>South San Francisco, CA</i>	COPD	Phase I <a href="http://www.gsk.com">www.gsk.com</a> <a href="http://www.theravance.com">www.theravance.com</a>
GSK2256294 (soluble epoxide hydrolase inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
GSK2269557 (p38 kinase inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD and asthma	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
GSK2793660 (cathepsin C inhibitor)	GlaxoSmithKline <i>Research Triangle Park, NC</i>	bronchiectasis	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
GSK961081 (muscarinic antagonist/ beta2 agonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Theravance Biopharma U.S. <i>South San Francisco, CA</i>	COPD	Phase II <a href="http://www.gsk.com">www.gsk.com</a> <a href="http://www.theravance.com">www.theravance.com</a>
<b>Incruse Ellipta</b> muscarinic acetylcholine antagonist	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	application submitted <a href="http://www.gsk.com">www.gsk.com</a>

## Chronic Obstructive Pulmonary Disease (COPD)

Product Name	Sponsor	Indication	Development Phase
JNJ-49095397 (RV568)	Janssen Research & Development <i>Raritan, NJ</i>	COPD	Phase II <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
losmapimod (oral p38 kinase inhibitor)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
MEDI8968 (anti-IL-1R mAb)	MedImmune <i>Gaithersburg, MD</i>	COPD	Phase II <a href="http://www.medimmune.com">www.medimmune.com</a>
NVA237 (glycopyrrolate inhalation)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	COPD	Phase III <a href="http://www.novartis.com">www.novartis.com</a>
olodaterol	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	COPD	application submitted <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>
olodaterol/tiotropium bromide	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	COPD	Phase II <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>
PF-03715455	Pfizer <i>New York, NY</i>	COPD	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
PH-797804 (P38 inhibitor)	Pfizer <i>New York, NY</i>	COPD	Phase II <a href="http://www.pfizer.com">www.pfizer.com</a>
PT001 (glycopyrrolate inhalation aerosol)	Pearl Therapeutics <i>Redwood City, CA</i>	COPD	Phase III <a href="http://www.pearltherapeutics.com">www.pearltherapeutics.com</a>
PT003 (glycopyrrolate/formoterol inhalation aerosol)	Pearl Therapeutics <i>Redwood City, CA</i>	COPD	Phase III <a href="http://www.pearltherapeutics.com">www.pearltherapeutics.com</a>
PT010 (budesonide, glycopyrronium and formoterol inhalation aerosol)	Pearl Therapeutics <i>Redwood City, CA</i>	COPD	Phase I <a href="http://www.pearltherapeutics.com">www.pearltherapeutics.com</a>
PUR0200 (LAMA)	Pulmatrix <i>Lexington, MA</i>	COPD	Phase II <a href="http://www.pulmatrix.com">www.pulmatrix.com</a>
PUR118	Pulmatrix <i>Lexington, MA</i>	COPD	Phase I <a href="http://www.pulmatrix.com">www.pulmatrix.com</a>
QBM076	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	COPD	Phase I <a href="http://www.novartis.com">www.novartis.com</a>
quercetin (thromboxane A2 synthase inhibitor)	Quercegen Pharmaceuticals <i>Sudbury, MA</i>	COPD	Phase II <a href="http://www.quercegen.com">www.quercegen.com</a>

## Chronic Obstructive Pulmonary Disease (COPD)

Product Name	Sponsor	Indication	Development Phase
QVA149 (glycopyrrolate/indacaterol inhalation)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	COPD	Phase III <a href="http://www.novartis.com">www.novartis.com</a>
SUN-101 (long-acting muscarinic receptor antagonist)	Sunovion <i>Marlborough, MA</i>	COPD	Phase II <a href="http://www.sunovion.com">www.sunovion.com</a>
TD-4208 (LAMA)	Theravance Biopharma U.S. <i>South San Francisco, CA</i>	COPD	Phase II <a href="http://www.theravance.com">www.theravance.com</a>
TRN-157 (LAMA)	Theron Pharmaceuticals <i>Sunnyvale, CA</i>	COPD	Phase I <a href="http://www.theronpharma.com">www.theronpharma.com</a>
vilanterol (long-acting beta2 agonist)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	COPD	Phase III <a href="http://www.gsk.com">www.gsk.com</a>

## Depression

Product Name	Sponsor	Indication	Development Phase
ademetonine (MSI-195)	MSI Methylation Sciences <i>Burnaby, Canada</i>	major depressive disorder	Phase II <a href="http://www.methylationsciences.com">www.methylationsciences.com</a>
ALKS 5461 (buprenorphine/samidorphan)	Alkermes <i>Waltham, MA</i>	major depressive disorder (Fast Track)	Phase III <a href="http://www.alkermes.com">www.alkermes.com</a>
amitifadine (triple reuptake inhibitor)	Euthymics Bioscience <i>Cambridge, MA</i>	major depressive disorder	Phase II/III <a href="http://www.euthymics.com">www.euthymics.com</a>
armodafinil	Teva Pharmaceutical <i>North Wales, PA</i>	major depressive disorder associated with bipolar 1 disorder	Phase III completed <a href="http://www.tevapharm.com">www.tevapharm.com</a>
AVP-786 (deuterium modified dextromethorphan and ultra-low dose quinidine)	Avanir Pharmaceuticals <i>Aliso Viejo, CA</i> Concert Pharmaceuticals <i>Lexington, MA</i>	treatment-resistant depression	Phase I completed <a href="http://www.avanir.com">www.avanir.com</a> <a href="http://www.concertpharma.com">www.concertpharma.com</a>
AZD6423 (NMDA modulator)	AstraZeneca <i>Wilmington, DE</i>	suicidal ideation	Phase I <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
<b>Botox</b> <sup>®</sup> onabotulinumtoxinA	Allergan <i>Irvine, CA</i>	major depressive disorder	Phase II <a href="http://www.allergan.com">www.allergan.com</a>

## Depression

Product Name	Sponsor	Indication	Development Phase
brexpiprazole (dopamine partial agonist)	Lundbeck <i>Deerfield, IL</i> Otsuka Pharmaceutical <i>Rockville, MD</i>	major depressive disorder (adjunctive treatment) (see also Alzheimer's)	Phase III <a href="http://www.lundbeck.com">www.lundbeck.com</a> <a href="http://www.otsuka.com">www.otsuka.com</a>
cariprazine	Forest Laboratories <i>New York, NY</i>	bipolar depression, major depressive disorder	Phase II <a href="http://www.frx.com">www.frx.com</a>
CERC-301 (NR2B antagonist)	Cerecor <i>Baltimore, MD</i>	major depressive disorder (Fast Track)	Phase II <a href="http://www.cerecor.com">www.cerecor.com</a>
		active suicidal ideation	Phase II <a href="http://www.cerecor.com">www.cerecor.com</a>
DSP-1053 (serotonin uptake inhibitor)	Sunovion <i>Marlborough, MA</i>	major depressive disorder	Phase I <a href="http://www.sunovion.com">www.sunovion.com</a>
esketamine (intranasal)	Janssen Research & Development <i>Raritan, NJ</i>	treatment-resistant major depressive disorder (Fast Track)	Phase II <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
GLYX-13	Naurex <i>Evanston, IL</i>	major depressive disorder (Fast Track)	Phase II <a href="http://www.naurex.com">www.naurex.com</a>
HT-2157 (GALR3 antagonist)	Dart NeuroScience <i>San Diego, CA</i>	major depressive disorder	Phase II <a href="http://www.dartneuroscience.com">www.dartneuroscience.com</a>
JNJ-42847922	Janssen Research & Development <i>Raritan, NJ</i>	major depressive disorder	Phase I <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
<b>Latuda</b> <sup>®</sup> lurasidone	Sunovion <i>Marlborough, MA</i>	major depressive disorder with mixed features	Phase III <a href="http://www.sunovion.com">www.sunovion.com</a>
LY03005	Luye America Pharmaceuticals <i>Princeton, NJ</i>	major depressive disorder	Phase I <a href="http://www.luye.cn">www.luye.cn</a>
LY2940094 (NOC-1 antagonist)	Eli Lilly <i>Indianapolis, IN</i>	major depressive disorder	Phase II <a href="http://www.lilly.com">www.lilly.com</a>
MIN-117 (5-HT1A/5-HTT receptor antagonist)	Minerva Neurosciences <i>Cambridge, MA</i>	major depressive disorder	Phase II <a href="http://www.minervaneurosciences.com">www.minervaneurosciences.com</a>
NRX-1074 (NMDA receptor agonist)	Naurex <i>Evanston, IL</i>	major depressive disorder	Phase I <a href="http://www.naurex.com">www.naurex.com</a>
NSI-189 (stimulating neurogenesis)	Neuralstem <i>Germantown, MD</i>	major depressive disorder	Phase I <a href="http://www.neuralstem.com">www.neuralstem.com</a>

## Depression

Product Name	Sponsor	Indication	Development Phase
RG1578 (mGluR2)	Roche <i>Nutley, NJ</i>	major depressive disorder	Phase II <a href="http://www.roche.com">www.roche.com</a>
RG7090 (mGluR5 antagonist)	Roche <i>Nutley, NJ</i>	treatment-resistant depression	Phase II <a href="http://www.roche.com">www.roche.com</a>
RO4995819	Roche <i>Nutley, NJ</i>	major depressive disorder	Phase II <a href="http://www.roche.com">www.roche.com</a>
<b>Rozerem</b> <sup>®</sup> ramelteon (sublingual formulation)	Takeda Pharmaceutical <i>Deerfield, IL</i>	acute depressive episodes associated with bipolar 1 disorder	Phase III <a href="http://www.takeda.com">www.takeda.com</a>
SEP-363856	Sunovion <i>Marlborough, MA</i>	major depressive disorder	Phase I <a href="http://www.sunovion.com">www.sunovion.com</a>
tedatioxetine	Lundbeck <i>Deerfield, IL</i> Takeda Pharmaceutical <i>Deerfield, IL</i>	major depressive disorder	Phase II <a href="http://www.lundbeck.com">www.lundbeck.com</a> <a href="http://www.takeda.com">www.takeda.com</a>

## Diabetes, Type 1 and Type 2 Diabetes

Product Name	Sponsor	Indication	Development Phase
<b>Afrezza</b> <sup>®</sup> insulin inhalation	MannKind <i>Valencia, CA</i>	type 1 diabetes, type 2 diabetes	application submitted <a href="http://www.mannkindcorp.com">www.mannkindcorp.com</a>
alpha-1 antitrypsin (AAT) (serine proteinase inhibitor)	Omni Bio Pharmaceutical <i>Greenwood Village, CO</i>	type 1 diabetes	Phase I/II <a href="http://www.omnibiopharma.com">www.omnibiopharma.com</a>
AMG 876 (fusion protein)	Amgen <i>Thousand Oaks, CA</i>	type 2 diabetes	Phase I <a href="http://www.amgen.com">www.amgen.com</a>
analog insulin-PH20	Halozyme Therapeutics <i>San Diego, CA</i>	type 1 diabetes, type 2 diabetes	Phase II <a href="http://www.halozyme.com">www.halozyme.com</a>
BI-187004 CL	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	type 2 diabetes	Phase I <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>
BIOD-123 (RHI-based ultra-rapid-acting insulin)	Biodel <i>Danbury, CT</i>	type 1 diabetes	Phase II <a href="http://www.biodel.com">www.biodel.com</a>

## Diabetes, Type 1 and Type 2 Diabetes

Product Name	Sponsor	Indication	Development Phase
BIOD-531 (RHI-based concentrated ultra-rapid-acting insulin)	Biodel <i>Danbury, CT</i>	type 2 diabetes	Phase I <a href="http://www.biodel.com">www.biodel.com</a>
BT1320	Boston Therapeutics <i>Manchester, NH</i>	type 2 diabetes	Phase II <a href="http://www.bostonti.com">www.bostonti.com</a>
<b>Bydureon</b> <sup>®</sup> exenatide weekly suspension	AstraZeneca <i>Wilmington, DE</i>	type 2 diabetes	Phase III <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
canagliflozin/metformin extended-release fixed-dose combination	Janssen Research & Development <i>Raritan, NJ</i>	type 2 diabetes	Phase III <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
canagliflozin/metformin immediate-release fixed-dose combination	Janssen Research & Development <i>Raritan, NJ</i>	type 2 diabetes	application submitted <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
CJC-1134-PC (GLP-1 stimulant)	ConjuChem <i>Los Angeles, CA</i>	type 2 diabetes	Phase II <a href="http://www.conjuchem.com">www.conjuchem.com</a>
dapagliflozin/saxagliptin fixed-dose combination	AstraZeneca <i>Wilmington, DE</i>	diabetes	Phase III <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
diabetes biologic	Eli Lilly <i>Indianapolis, IN</i>	diabetes	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
diabetes biologic	Eli Lilly <i>Indianapolis, IN</i>	diabetes	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
diabetes biologic	Eli Lilly <i>Indianapolis, IN</i>	diabetes	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
diabetes biologic	Eli Lilly <i>Indianapolis, IN</i>	diabetes	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
diabetes NCE	Eli Lilly <i>Indianapolis, IN</i>	diabetes	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
DS-1150b (GLUT4 stimulant)	Daiichi Sankyo <i>Parsippany, NJ</i>	type 2 diabetes	Phase I completed <a href="http://www.daiichisankyo.com">www.daiichisankyo.com</a>
DS-7309 (glucokinase activator)	Daiichi Sankyo <i>Parsippany, NJ</i>	type 2 diabetes	Phase I <a href="http://www.daiichisankyo.com">www.daiichisankyo.com</a>
DS-8500 (GPR119 agonist)	Daiichi Sankyo <i>Parsippany, NJ</i>	diabetes	Phase I <a href="http://www.daiichisankyo.com">www.daiichisankyo.com</a>

## Diabetes, Type 1 and Type 2 Diabetes

Product Name	Sponsor	Indication	Development Phase
dulaglutide (GLP-1 agonist)	Eli Lilly <i>Indianapolis, IN</i>	type 2 diabetes	application submitted <a href="http://www.lilly.com">www.lilly.com</a>
DV-0100 (dendritic cell vaccine) ORPHAN DRUG	DiaVacs <i>Edgewater, NJ</i>	type 1 diabetes	Phase II <a href="http://www.diavac.us.com">www.diavac.us.com</a>
EGT 0001442 (SGLT2 inhibitor)	Theracos <i>Marlborough, MA</i>	type 2 diabetes	Phase II <a href="http://www.theracos.com">www.theracos.com</a>
icosapentaenoic acid/metformin fixed-dose combination (TP-101)	Thetis Pharmaceuticals <i>Southport, CT</i>	type 2 diabetes (see also heart disease)	Phase I <a href="http://www.thetispharma.com">www.thetispharma.com</a>
empagliflozin (SGLT2 inhibitor)	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> Eli Lilly <i>Indianapolis, IN</i>	type 2 diabetes	application submitted <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a> <a href="http://www.lilly.com">www.lilly.com</a>
empagliflozin/linagliptin fixed-dose combination	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> Eli Lilly <i>Indianapolis, IN</i>	type 2 diabetes	application submitted <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a> <a href="http://www.lilly.com">www.lilly.com</a>
empagliflozin/metformin fixed-dose combination	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> Eli Lilly <i>Indianapolis, IN</i>	type 2 diabetes	Phase I <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a> <a href="http://www.lilly.com">www.lilly.com</a>
ertugliflozin (SGLT2 inhibitor)	Merck <i>Whitehouse Station, NJ</i> Pfizer <i>New York, NY</i>	type 2 diabetes	Phase III <a href="http://www.merck.com">www.merck.com</a> <a href="http://www.pfizer.com">www.pfizer.com</a>
glucagon-R antagonist (LY2409021)	Eli Lilly <i>Indianapolis, IN</i>	type 2 diabetes	Phase II <a href="http://www.lilly.com">www.lilly.com</a>
GSK2330672 (iBAT inhibitor)	GlaxoSmithKline <i>Research Triangle Park, NC</i>	type 2 diabetes	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
HE3286	Harbor Biosciences <i>San Diego, CA</i>	type 2 diabetes	Phase II <a href="http://www.harbortx.com">www.harbortx.com</a>
HIP-2B (human pro-islet peptide)	CureDM <i>Wilmington, DE</i>	type 1 diabetes, type 2 diabetes	Phase I <a href="http://www.curedm.com">www.curedm.com</a>
HM11260C (exenatide long-acting)	Hanmi Pharmaceutical <i>Seoul, South Korea</i>	type 2 diabetes	Phase II <a href="http://www.hanmipharm.com">www.hanmipharm.com</a>

## Diabetes, Type 1 and Type 2 Diabetes

Product Name	Sponsor	Indication	Development Phase
HM12460A (long-acting insulin)	Hanmi Pharmaceutical <i>Seoul, South Korea</i>	type 1 diabetes, type 2 diabetes	Phase I <a href="http://www.hanmipharm.com">www.hanmipharm.com</a>
insulin aspart faster-acting (NN1218)	Novo Nordisk <i>Plainsboro, NJ</i>	type 1 diabetes, type 2 diabetes	Phase III <a href="http://www.novonordisk.com">www.novonordisk.com</a>
insulin biosimilar	Harvest Moon Pharmaceuticals <i>Falls Church, VA</i>	diabetes	Phase III <a href="http://www.harvestmoonpharma.com">www.harvestmoonpharma.com</a>
insulin biosimilar	Sanofi US <i>Bridgewater, NJ</i>	diabetes	Phase I <a href="http://www.sanofi.com">www.sanofi.com</a>
insulin glargine biosimilar	Harvest Moon Pharmaceuticals <i>Falls Church, VA</i>	diabetes	in clinical trials <a href="http://www.harvestmoonpharma.com">www.harvestmoonpharma.com</a>
insulin glargine biosimilar	Wockhardt <i>Mumbai, India</i>	type 1 diabetes	Phase I completed <a href="http://www.wockhardt.com">www.wockhardt.com</a>
insulin lispro (LY275585)	Eli Lilly <i>Indianapolis, IN</i>	type 1 diabetes, type 2 diabetes	in clinical trials <a href="http://www.lilly.com">www.lilly.com</a>
insulin peglispro (LY2605541)	Eli Lilly <i>Indianapolis, IN</i>	type 1 diabetes, type 2 diabetes	Phase III <a href="http://www.lilly.com">www.lilly.com</a>
ISIS-GCCRRx (antisense oligonucleotide)	Isis Pharmaceuticals <i>Carlsbad, CA</i>	type 2 diabetes	Phase II <a href="http://www.isispharm.com">www.isispharm.com</a>
ISIS-GCRRx (antisense oligonucleotide)	Isis Pharmaceuticals <i>Carlsbad, CA</i>	type 2 diabetes	Phase II <a href="http://www.isispharm.com">www.isispharm.com</a>
ISIS-PTP1BRx (antisense oligonucleotide)	Isis Pharmaceuticals <i>Carlsbad, CA</i>	type 2 diabetes	Phase II <a href="http://www.isispharm.com">www.isispharm.com</a>
ITCA 650 (exenatide subcutaneous implant)	Intarcia Therapeutics <i>Boston, MA</i>	type 2 diabetes	Phase III <a href="http://www.intarcia.com">www.intarcia.com</a>
JTT-251	Akros Pharma <i>Princeton, NJ</i>	type 2 diabetes	Phase I <a href="http://www.akrospharma.com">www.akrospharma.com</a>
JTT-252	Akros Pharma <i>Princeton, NJ</i>	type 2 diabetes	Phase I <a href="http://www.akrospharma.com">www.akrospharma.com</a>
JTT-851 (G protein-coupled receptor 40 agonist)	Akros Pharma <i>Princeton, NJ</i>	type 2 diabetes	Phase II <a href="http://www.akrospharma.com">www.akrospharma.com</a>
KD026 (MTP inhibitor)	Kadmon Pharmaceuticals <i>New York, NY</i>	type 2 diabetes	Phase II <a href="http://www.kadmon.com">www.kadmon.com</a>

## Diabetes, Type 1 and Type 2 Diabetes

Product Name	Sponsor	Indication	Development Phase
LAI287 (NN1436)	Novo Nordisk <i>Plainsboro, NJ</i>	type 1 diabetes, type 2 diabetes	Phase I <a href="http://www.novonordisk.com">www.novonordisk.com</a>
LGD-6972 (glucagon receptor antagonist)	Ligand Pharmaceuticals <i>La Jolla, CA</i>	type 2 diabetes	Phase I <a href="http://www.ligand.com">www.ligand.com</a>
LIK066 (SGLT 1/2 inhibitor)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	type 2 diabetes	Phase II <a href="http://www.novartis.com">www.novartis.com</a>
linagliptin/pioglitazone fixed-dose combination	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> Eli Lilly <i>Indianapolis, IN</i>	type 2 diabetes	Phase III completed <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a> <a href="http://www.lilly.com">www.lilly.com</a>
<b>LixiLan</b> lixisenatide/insulin glargine fixed ratio	Sanofi US <i>Bridgewater, NJ</i>	type 2 diabetes	Phase III <a href="http://www.sanofi.com">www.sanofi.com</a>
luseogliflozin (TS-071)	Taisho Pharmaceutical <i>Tokyo, Japan</i>	type 2 diabetes	Phase I <a href="http://www.taisho.co.jp">www.taisho.co.jp</a>
LX4211 (SGLT1/SGLT2 inhibitor)	Lexicon Pharmaceuticals <i>The Woodlands, TX</i>	type 1 diabetes, type 2 diabetes	Phase II <a href="http://www.lexgen.com">www.lexgen.com</a>
<b>Lyxumia</b> <sup>®</sup> lixisenatide	Sanofi US <i>Bridgewater, NJ</i>	type 2 diabetes	Phase III <a href="http://www.sanofi.com">www.sanofi.com</a>
MBX-2982	CymaBay Therapeutics <i>Hayward, CA</i>	type 2 diabetes	Phase II <a href="http://www.cymabay.com">www.cymabay.com</a>
mesenchymal precursor cells (MPC)	Mesoblast <i>Melbourne, Australia</i>	type 2 diabetes	Phase II <a href="http://www.mesoblast.com">www.mesoblast.com</a>
MK-1293 (insulin glargine biosimilar)	Merck <i>Whitehouse Station, NJ</i>	type 1 diabetes, type 2 diabetes	Phase III <a href="http://www.merck.com">www.merck.com</a>
MK-8521	Merck <i>Whitehouse Station, NJ</i>	type 2 diabetes	Phase I <a href="http://www.merck.com">www.merck.com</a>
MK-8666	Merck <i>Whitehouse Station, NJ</i>	type 2 diabetes	Phase I <a href="http://www.merck.com">www.merck.com</a>
MSDC-0602 (mTOT modulator)	Metabolic Solutions Development <i>Kalamazoo, MI</i>	type 2 diabetes	Phase II <a href="http://www.msdrx.com">www.msdrx.com</a>
new insulin glargine biosimilar (LY2963016)	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i> Eli Lilly <i>Indianapolis, IN</i>	type 1 diabetes, type 2 diabetes	application submitted <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a> <a href="http://www.lilly.com">www.lilly.com</a>

## Diabetes, Type 1 and Type 2 Diabetes

Product Name	Sponsor	Indication	Development Phase
<b>NewMet™</b> metformin delayed release	Elcelyx Therapeutics <i>San Diego, CA</i>	type 2 diabetes	Phase II <a href="http://www.elcelyx.com">www.elcelyx.com</a>
NGM 282	NGM Biopharmaceuticals <i>South San Francisco, CA</i>	type 2 diabetes	Phase II <a href="http://www.ngmbio.com">www.ngmbio.com</a>
NM504 (microbiome modulator)	MicroBiome Therapeutics <i>Broomfield, CO</i>	metformin-intolerant type 2 diabetes	Phase 0 <a href="http://www.mbiome.com">www.mbiome.com</a>
NN1953 (oral insulin)	Novo Nordisk <i>Plainsboro, NJ</i>	type 1 diabetes, type 2 diabetes	Phase I <a href="http://www.novonordisk.com">www.novonordisk.com</a>
NN9924	Novo Nordisk <i>Plainsboro, NJ</i>	type 2 diabetes	Phase II <a href="http://www.novonordisk.com">www.novonordisk.com</a>
NN9926	Novo Nordisk <i>Plainsboro, NJ</i>	type 2 diabetes	Phase I <a href="http://www.novonordisk.com">www.novonordisk.com</a>
NN9927	Novo Nordisk <i>Plainsboro, NJ</i>	type 2 diabetes	Phase I <a href="http://www.novonordisk.com">www.novonordisk.com</a>
NN9928	Novo Nordisk <i>Plainsboro, NJ</i>	type 2 diabetes	Phase I <a href="http://www.novonordisk.com">www.novonordisk.com</a>
omarigliptin (DPP-4 inhibitor)	Merck <i>Whitehouse Station, NJ</i>	type 2 diabetes	Phase III <a href="http://www.merck.com">www.merck.com</a>
<b>Oral-Lyn®</b> oral insulin	Generex Biotechnology <i>Toronto, Canada</i>	type 1 diabetes	Phase III <a href="http://www.generex.com">www.generex.com</a>
ORMD 0801 (oral insulin capsule)	Oramed <i>Jerusalem, Israel</i>	type 1 diabetes, type 2 diabetes	Phase II <a href="http://www.oramed.com">www.oramed.com</a>
oxyntomodulin peptide	Eli Lilly <i>Indianapolis, IN</i>	diabetes	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
P7435	Piramal Enterprises <i>Mumbai, India</i>	diabetes	Phase I <a href="http://www.piramal.com">www.piramal.com</a>
P11187	Piramal Enterprises <i>Mumbai, India</i>	type 2 diabetes	Phase I <a href="http://www.piramal.com">www.piramal.com</a>
PB1023 (weekly GLP-1R agonist)	PhaseBio Pharmaceuticals <i>Malvern, PA</i>	type 2 diabetes	Phase II <a href="http://www.phasebio.com">www.phasebio.com</a>
PE0139 (basal native insulin)	PhaseBio Pharmaceuticals <i>Malvern, PA</i>	type 2 diabetes	Phase I <a href="http://www.phasebio.com">www.phasebio.com</a>

## Diabetes, Type 1 and Type 2 Diabetes

Product Name	Sponsor	Indication	Development Phase
PEG-FGF21 (BMS-986036)	Ambrx <i>San Diego, CA</i> Bristol-Myers Squibb <i>Princeton, NJ</i>	type 2 diabetes	Phase I <a href="http://www.ambrx.com">www.ambrx.com</a> <a href="http://www.bms.com">www.bms.com</a>
Peptide p277 ORPHAN DRUG	Andromeda Biotech <i>Yavne, Israel</i>	type 1 diabetes	Phase III <a href="http://www.andromedabio.com">www.andromedabio.com</a>
PF-04937319 (partial glucokinase activator)	Pfizer <i>New York, NY</i>	type 2 diabetes	Phase II <a href="http://www.pfizer.com">www.pfizer.com</a>
PF-05175157 (acetyl-CoA carboxylase inhibitor)	Pfizer <i>New York, NY</i>	type 2 diabetes	Phase II <a href="http://www.pfizer.com">www.pfizer.com</a>
PF-06291874	Pfizer <i>New York, NY</i>	type 2 diabetes	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
PF-06342674	Pfizer <i>New York, NY</i>	type 1 diabetes	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
ranolazine extended release	Gilead Sciences <i>Foster City, CA</i>	type 2 diabetes	Phase III <a href="http://www.gilead.com">www.gilead.com</a>
remogliflozin-etabonate (SGLT2 inhibitor)	BHV Pharma <i>Research Triangle Park, NC</i>	type 2 diabetes	Phase II <a href="http://www.bhvpharma.com">www.bhvpharma.com</a>
RG7697 (dual agonist [GLP and GIP] peptide analogue)	Roche <i>Nutley, NJ</i>	type 2 diabetes	Phase I <a href="http://www.roche.com">www.roche.com</a>
RM 493 (MC4R peptide therapeutic)	Rhythm Pharmaceuticals <i>Boston, MA</i>	diabetes	Phase II <a href="http://www.rhythmtx.com">www.rhythmtx.com</a>
<b>Ryzodeq</b> <sup>®</sup> insulin degludec/insulin aspart	Novo Nordisk <i>Plainsboro, NJ</i>	type 1 diabetes, type 2 diabetes	application submitted <a href="http://www.novonordisk.com">www.novonordisk.com</a>
S-707106 (insulin sensitizer)	Shionogi <i>Florham Park, NJ</i>	type 2 diabetes	Phase II <a href="http://www.shionogi.com">www.shionogi.com</a>
secukinumab (IL-17 inhibitor)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	type 1 diabetes (see also arthritis)	Phase I <a href="http://www.novartis.com">www.novartis.com</a>
semaglutide (NN9535)	Novo Nordisk <i>Plainsboro, NJ</i>	type 2 diabetes	Phase III <a href="http://www.novonordisk.com">www.novonordisk.com</a>
teneligliptin (DPP-4 inhibitor)	Mitsubishi Tanabe Pharma America <i>Jersey City, NJ</i>	type 2 diabetes	Phase I <a href="http://www.mt-pharma-america.com">www.mt-pharma-america.com</a>

## Diabetes, Type 1 and Type 2 Diabetes

Product Name	Sponsor	Indication	Development Phase
teplizumab (anti-CD3 mAb) ORPHAN DRUG	Macrogenics <i>Rockville, MD</i>	type 1 diabetes	Phase III <a href="http://www.macrogenics.com">www.macrogenics.com</a>
TOL-3021 (antigen-specific immunotherapeutic vaccine)	Tolerion <i>Portola Valley, CA</i>	type 1 diabetes	Phase II <a href="http://www.tolerioninc.com">www.tolerioninc.com</a>
trelagliptin (DPP-4 inhibitor)	Takeda Pharmaceuticals <i>Deerfield, IL</i>	type 2 diabetes	Phase II <a href="http://www.takeda.com">www.takeda.com</a>
<b>Tresiba</b> <sup>®</sup> insulin degludec	Novo Nordisk <i>Plainsboro, NJ</i>	type 1 diabetes, type 2 diabetes	application submitted <a href="http://www.novonordisk.com">www.novonordisk.com</a>
TRI-102	Tris Pharma <i>Monmouth Junction, NJ</i>	type 2 diabetes	in clinical trials <a href="http://www.trispharma.com">www.trispharma.com</a>
TTP054 (GLP-1 receptor agonist)	TransTech Pharma <i>High Point, NC</i>	type 2 diabetes	Phase II <a href="http://www.ttpharma.com">www.ttpharma.com</a>
TTP399 (glucokinase inhibitor)	TransTech Pharma <i>High Point, NC</i>	type 2 diabetes	Phase I/II <a href="http://www.ttpharma.com">www.ttpharma.com</a>
TTP814 (PTP-1B inhibitor)	TransTech Pharma <i>High Point, NC</i>	type 2 diabetes	Phase I/II <a href="http://www.ttpharma.com">www.ttpharma.com</a>
U300 (insulin glargine)	Sanofi US <i>Bridgewater, NJ</i>	type 1 diabetes, type 2 diabetes	Phase III <a href="http://www.sanofi.com">www.sanofi.com</a>
<b>U-Strip</b> <sup>™</sup> insulin transdermal ultrasonic patch	Transdermal Specialties <i>Norwalk, CT</i>	type 1 diabetes, type 2 diabetes	Phase I <a href="http://www.transdermalspecialties.com">www.transdermalspecialties.com</a>
<b>Victoza</b> <sup>®</sup> liraglutide	Novo Nordisk <i>Plainsboro, NJ</i>	type 1 diabetes	Phase III <a href="http://www.novonordisk.com">www.novonordisk.com</a>
VK0612 (FBPase inhibitor)	Viking Therapeutics <i>La Jolla, CA</i>	type 2 diabetes	Phase II <a href="http://www.vikingtherapeutics.com">www.vikingtherapeutics.com</a>
<b>Xigduo</b> <sup>™</sup> XR FDC dapagliflozin/metformin fixed-dose combination	AstraZeneca <i>Wilmington, DE</i>	type 2 diabetes	application submitted <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
<b>Xultophy</b> <sup>®</sup> insulin degludec/liraglutide (NN9068)	Novo Nordisk <i>Plainsboro, NJ</i>	type 2 diabetes	Phase III <a href="http://www.novonordisk.com">www.novonordisk.com</a>

## Glaucoma

Product Name	Sponsor	Indication	Development Phase
AC 262271 (muscarinic receptor agonist)	ACADIA Pharmaceuticals <i>San Diego, CA</i> Allergan <i>Irvine, CA</i>	glaucoma	Phase I <a href="http://www.acadia-pharm.com">www.acadia-pharm.com</a> <a href="http://www.allergan.com">www.allergan.com</a>
AMA0076 (ROCK inhibitor)	Amakem <i>Diepenbeek, Belgium</i>	glaucoma	Phase II <a href="http://www.amakem.com">www.amakem.com</a>
bimatoprost sustained release	Allergan <i>Irvine, CA</i>	glaucoma	Phase II <a href="http://www.allergan.com">www.allergan.com</a>
bimatoprost/brimonidine fixed-dose combination	Allergan <i>Irvine, CA</i>	glaucoma	Phase II completed <a href="http://www.allergan.com">www.allergan.com</a>
brinzolamide/timolol fixed-dose combination	Alcon <i>Fort Worth, TX</i>	glaucoma	Phase III completed <a href="http://www.alcon.com">www.alcon.com</a>
CF101 (adenosine A3 receptor agonist)	Can-Fite Pharma <i>Petah-Tikva, Israel</i> OphthaliX <i>Carson City, NV</i>	glaucoma (see also arthritis)	Phase II <a href="http://www.opthalix.com">www.opthalix.com</a>
DE-117 (EP2 receptor agonist)	Santen Pharmaceutical <i>Emeryville, CA</i>	glaucoma	Phase II <a href="http://www.santeninc.com">www.santeninc.com</a>
dorzolamide/latanoprost fixed-dose combination	Alleanza Pharmaceuticals <i>Tampa, FL</i>	glaucoma	Phase II completed
latanoprost punctal plug	Mati Therapeutics <i>Austin, TX</i>	glaucoma	Phase II <a href="http://www.matitherapeutics.com">www.matitherapeutics.com</a>
latanoprost sustained released (bioerodible)	Pfizer <i>New York, NY</i> pSivida <i>Watertown, MA</i>	glaucoma	Phase I/II <a href="http://www.pfizer.com">www.pfizer.com</a> <a href="http://www.psivida.com">www.psivida.com</a>
latanoprostene bunod	Bausch & Lomb <i>Rochester, NY</i>	glaucoma	Phase III <a href="http://www.bausch.com">www.bausch.com</a>
ONO-9054 (prostaglandin FP/EP3 receptor agonist)	Ono Pharmaceutical <i>Osaka, Japan</i>	open-angle glaucoma	Phase I <a href="http://www.ono.co.jp">www.ono.co.jp</a>
OPA-6566 (adenosine A2A receptor agonist)	Acucela <i>Seattle, WA</i> Otsuka Pharmaceutical <i>Tokyo, Japan</i>	glaucoma	Phase I/II <a href="http://www.acucela.com">www.acucela.com</a>

## Glaucoma

Product Name	Sponsor	Indication	Development Phase
QPI-1007 (RNA interference)	Quark Pharmaceuticals <i>Fremont, CA</i>	angle-closure glaucoma	Phase II <a href="http://www.quarkpharma.com">www.quarkpharma.com</a>
<b>Rhopressa™</b> ROCK/NET inhibitor	Aerie Pharmaceuticals <i>Bedminster, NJ</i>	glaucoma	Phase II <a href="http://www.aeriepharma.com">www.aeriepharma.com</a>
<b>Roclatan™</b> ROCK/NET inhibitor and latanaprost	Aerie Pharmaceuticals <i>Bedminster, NJ</i>	glaucoma	Phase II <a href="http://www.aeriepharma.com">www.aeriepharma.com</a>
trabodенoson	Inotek Pharmaceuticals <i>Lexington, MA</i>	glaucoma	Phase II <a href="http://www.inotekcorp.com">www.inotekcorp.com</a>
travoprost punctal plug	Ocular Therapeutix <i>Bedford, MA</i>	glaucoma	Phase II <a href="http://www.ocutx.com">www.ocutx.com</a>
VISION 5 (timolol insert)	ForSight Vision5 <i>Menlo Park, CA</i>	glaucoma	Phase II <a href="http://www.forsightvision5.com">www.forsightvision5.com</a>

## Heart Disease

Product Name	Sponsor	Indication	Development Phase
<b>AdipoCell™</b> adipose-derived autologous stem cell therapy	Bioheart <i>Sunrise, FL</i>	heart failure (see also COPD)	Phase I/II <a href="http://www.bioheartinc.com">www.bioheartinc.com</a>
AEM-28	Lipimetix Development <i>Natick, MA</i>	hyperlipidemia	Phase I <a href="http://www.lipimetix.com">www.lipimetix.com</a>
alirocumab (anti-PCSK-9 mAb)	Regeneron Pharmaceuticals <i>Tarrytown, NY</i> Sanofi US <i>Bridgewater, NJ</i>	hypercholesterolemia	Phase III <a href="http://www.regeneron.com">www.regeneron.com</a> <a href="http://www.sanofi.com">www.sanofi.com</a>
amlodipine/telmisartan/ hydrochlorothiazide fixed-dose combination	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	hypertension	Phase I <a href="http://www.boehringer-ingenelheim.com">www.boehringer-ingenelheim.com</a>
AMR102 (ethyl eicosapentaenoic acid/rosu- vastatin fixed-dose combination)	Amarin <i>Bedminster, NJ</i>	hyperlipidemia	Phase I completed <a href="http://www.amarincorp.com">www.amarincorp.com</a>
anacetrapib (MK-0859)	Merck <i>Whitehouse Station, NJ</i>	atherosclerosis, hypercholesterolemia	Phase III <a href="http://www.merck.com">www.merck.com</a>
ANX-042 (natriuretic peptide)	Anexon <i>Cambridge, MA</i>	heart failure	Phase I completed

## Heart Disease

Product Name	Sponsor	Indication	Development Phase
AZD1772/RDX5791 (NHE3 inhibitor)	Ardelyx <i>Fremont, CA</i> AstraZeneca <i>Wilmington, DE</i>	heart failure (see also chronic kidney disease)	Phase II <a href="http://www.ardelyx.com">www.ardelyx.com</a> <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
BAY 98-07106 (candesartan cilexetil/nifedipine fixed-dose combination)	Bayer HealthCare Pharmaceuticals <i>Whippany, NJ</i>	essential hypertension	Phase III <a href="http://www.bayerpharma.com">www.bayerpharma.com</a>
BAY 10-67197 (partial adenosine A1 agonist)	Bayer HealthCare Pharmaceuticals <i>Whippany, NJ</i>	heart failure	Phase II <a href="http://www.bayerpharma.com">www.bayerpharma.com</a>
BAY 11-42524 (chymase inhibitor)	Bayer HealthCare Pharmaceuticals <i>Whippany, NJ</i>	heart failure	Phase I <a href="http://www.bayerpharma.com">www.bayerpharma.com</a>
<b>Bendavia™</b> mitochondrial permeability transition pore inhibitor	Stealth Peptides <i>Newton, MA</i>	chronic heart failure	Phase I <a href="http://www.stealthpeptides.com">www.stealthpeptides.com</a>
bococizumab (PCSK9 inhibitor)	Pfizer <i>New York, NY</i>	hyperlipidemia	Phase III <a href="http://www.pfizer.com">www.pfizer.com</a>
bucindolol	ARCA biopharma <i>Westminster, CO</i>	atrial fibrillation	Phase II/III <a href="http://www.arcabiopharma.com">www.arcabiopharma.com</a>
C3BS-CQR-1	Cardio3 Biosciences <i>Mont-Saint-Guibert, Belgium</i>	chronic heart failure	Phase III <a href="http://www.c3bs.com">www.c3bs.com</a>
CEP-41750 (mesenchymal precursor cells)	Teva Pharmaceutical <i>North Wales, PA</i>	chronic heart failure	Phase III <a href="http://www.tevapharm.com">www.tevapharm.com</a>
CLP-1001 (sodium-potassium-chloride symporter inhibitor)	Sorbent Therapeutics <i>Sunnyvale, CA</i>	chronic heart failure	Phase II <a href="http://www.sorbent.com">www.sorbent.com</a>
<b>Collatogene®</b> DNA plasmid with hepatocyte growth factor gene	AnGes <i>Bethesda, MD</i>	ischemic heart disease	Phase I <a href="http://www.anges-mg.com">www.anges-mg.com</a>
CT-2003 (eicosapentaenoic acid/niacin)	Catabasis Pharmaceuticals <i>Cambridge, MA</i>	refractory severe hypertriglyceridemia	Phase II <a href="http://www.catabasis.com">www.catabasis.com</a>
CXL-1427 (NHO donor therapeutic)	Cardioxyl Pharmaceuticals <i>Chapel Hill, NC</i>	acute decompensated heart failure	Phase I <a href="http://www.cardioxyl.com">www.cardioxyl.com</a>
dronedarone/ranolazine fixed-dose combination (late sodium current inhibitor)	Gilead Sciences <i>Foster City, CA</i>	paroxysmal atrial fibrillation	Phase II <a href="http://www.gilead.com">www.gilead.com</a>

## Heart Disease

Product Name	Sponsor	Indication	Development Phase
eicosapentaenoic acid/metformin fixed-dose combination (TP101)	Thetis Pharmaceuticals <i>Southport, CT</i>	hypertriglyceridemia (see also diabetes)	Phase I <a href="http://www.thetispharma.com">www.thetispharma.com</a>
ETC-1002 (ATP inhibitor/AMPK stimulator)	Esperion Therapeutics <i>Ann Arbor, MI</i>	hypercholesterolemia	Phase II <a href="http://www.esperion.com">www.esperion.com</a>
evolocumab (PCSK9 protein inhibitor)	Amgen <i>Thousand Oaks, CA</i>	hypercholesterolemia	Phase III <a href="http://www.amgen.com">www.amgen.com</a>
febuxostat	Takeda Pharmaceuticals <i>Deerfield, IL</i>	hypertension	Phase II <a href="http://www.takeda.com">www.takeda.com</a>
finerenone (MR antagonist)	Bayer HealthCare Pharmaceuticals <i>Whippany, NJ</i>	chronic heart failure (see also chronic kidney disease)	Phase II <a href="http://www.bayerpharma.com">www.bayerpharma.com</a>
GS-6615 (late sodium current inhibitor)	Gilead Sciences <i>Foster City, CA</i>	ventricular tachycardiaventricular fibrillation	Phase I <a href="http://www.gilead.com">www.gilead.com</a>
HL040 (atorvastatin/losartan fixed-dose combination)	HanAll Biopharma <i>Seoul, Korea</i>	hyperlipidemia, hypertension	Phase II <a href="http://www.hanall.co.kr">www.hanall.co.kr</a>
HS-25	Zhejiang Hisun Pharmaceutical <i>Zhejiang, China</i>	hypercholesterolemia	Phase II <a href="http://www.hisunusa.com">www.hisunusa.com</a>
hypertension NCE	Eli Lilly <i>Indianapolis, IN</i>	hypertension	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
ISIS-APOARx (antisense oligonucleotide)	Isis Pharmaceuticals <i>Carlsbad, CA</i>	hyperlipoproteinemias	Phase I <a href="http://www.isispharm.com">www.isispharm.com</a>
ISIS-APOCIIIrx (antisense oligonucleotide)	Isis Pharmaceuticals <i>Carlsbad, CA</i>	hypertriglyceridemia	Phase I <a href="http://www.isispharm.com">www.isispharm.com</a>
<b>Kynamro</b> <sup>®</sup> mipomersen	Genzyme <i>Cambridge, MA</i>	severe hyperlipoproteinemia type II	Phase III <a href="http://www.genzyme.com">www.genzyme.com</a>
LCZ696 (NEP inhibitor and angiotensin type 1 receptor blocker)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	heart failure (reduced ejection fraction) (see also chronic kidney disease)	Phase III <a href="http://www.novartis.com">www.novartis.com</a>
		heart failure (preserved ejection fraction)	Phase III <a href="http://www.novartis.com">www.novartis.com</a>
LFF269	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	essential hypertension	Phase II <a href="http://www.novartis.com">www.novartis.com</a>

## Heart Disease

Product Name	Sponsor	Indication	Development Phase
LMI 1195 (cardiac neuronal agent)	Lantheus Medical Imaging <i>N. Billerica, MA</i>	heart failure (diagnosis)	Phase I <a href="http://www.lantheus.com">www.lantheus.com</a>
LY3015014 (PCSK9 mAb)	Eli Lilly <i>Indianapolis, IN</i>	hypercholesterolemia	Phase II <a href="http://www.lilly.com">www.lilly.com</a>
MGL-3196 (thyroid hormone receptor beta agonist)	Madrigal Pharmaceuticals <i>Fort Washington, PA</i>	dyslipidemia, hypercholesterolemia	Phase I <a href="http://www.madrigalpharma.com">www.madrigalpharma.com</a>
<b>MyoCell</b> <sup>®</sup> autologous muscle stem cell therapy	Bioheart <i>Sunrise, FL</i>	severe heart damage in heart failure	Phase II/III <a href="http://www.bioheartinc.com">www.bioheartinc.com</a>
nebivolol/valsartan	Forest Laboratories <i>New York, NY</i>	hypertension	application submitted <a href="http://www.frx.com">www.frx.com</a>
omecamtiv mecarbil	Amgen <i>Thousand Oaks, CA</i> Cytokinetics <i>South San Francisco, CA</i>	heart failure	Phase II <a href="http://www.amgen.com">www.amgen.com</a> <a href="http://www.cytokinetics.com">www.cytokinetics.com</a>
ONO-4232 (prostaglandin E EP4 receptor agonist)	Ono Pharma USA <i>Trenton, NJ</i>	acute heart failure	Phase I <a href="http://www.ono.co.jp">www.ono.co.jp</a>
OPC 108459	Otsuka America Pharmaceutical <i>Rockville, MD</i>	paroxysmal and persistent atrial fibrillation	Phase I <a href="http://www.otsuka.com">www.otsuka.com</a>
perindopril/amlodipine fixed-dose combination	Symplmed Pharmaceutical <i>Cincinnati, OH</i>	hypertension	Phase III <a href="http://www.symplmed.com">www.symplmed.com</a>
PF-06678552	Pfizer <i>New York, NY</i>	hyperlipidemia	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
PRC-4016	Pronova BioPharma <i>Lysaker, Norway</i>	dyslipidemia, hypertriglyceridemia	Phase II <a href="http://www.basf.com">www.basf.com</a>
recombinant human neuregulin-1 beta	Zensun USA <i>San Diego, CA</i>	chronic heart failure	Phase II <a href="http://www.zensunusa.com">www.zensunusa.com</a>
recombinant neuregulin-1 (GGF-2)	Acorda Therapeutics <i>Ardsey, NY</i>	heart failure	Phase I <a href="http://www.acorda.com">www.acorda.com</a>
RG7652 (PCSK9 inhibitor)	Genentech <i>South San Francisco, CA</i>	hyperlipidemia	Phase II <a href="http://www.gene.com">www.gene.com</a>

## Heart Disease

Product Name	Sponsor	Indication	Development Phase
SERCA-2a gene therapy	Celladon <i>San Diego, CA</i>	heart failure (Breakthrough Therapy) (Fast Track)	Phase II <a href="http://www.celladon.com">www.celladon.com</a>
serelaxin	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	acute heart failure (Breakthrough Therapy) (Fast Track)	application submitted <a href="http://www.novartis.com">www.novartis.com</a>
		chronic heart failure	Phase II <a href="http://www.novartis.com">www.novartis.com</a>
sirolimus-eluting coronary stent	Svelte Medical Systems <i>New Providence, NJ</i>	ischemic heart disorder	Phase II <a href="http://www.sveltemedical.com">www.sveltemedical.com</a>
<b>Tekturna</b> <sup>®</sup> aliskiren	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	reduction of cardiovascular death and hospitalization in chronic heart failure	Phase III <a href="http://www.novartis.com">www.novartis.com</a>
TRV027	Forest Laboratories <i>New York, NY</i> Trevena <i>King of Prussia, PA</i>	acute heart failure	Phase II <a href="http://www.frx.com">www.frx.com</a> <a href="http://www.trevenainc.com">www.trevenainc.com</a>
ularitide	Cardioentis <i>Zug, Switzerland</i>	acute heart failure	Phase III <a href="http://www.cardioentis.com">www.cardioentis.com</a>
vanoxerine	ChanRx <i>Cleveland, OH</i>	atrial fibrillation	Phase II <a href="http://www.chanrx.com">www.chanrx.com</a>
<b>Vasomera</b> <sup>™</sup> vasoactive intestinal peptide type II receptor agonist	PhaseBio Pharmaceuticals <i>Malvern, PA</i>	essential hypertension	Phase I completed <a href="http://www.phasebio.com">www.phasebio.com</a>
vasopressin receptor antagonist	Bayer HealthCare Pharmaceutical <i>Whippany, NJ</i>	heart failure	Phase I <a href="http://www.bayerpharma.com">www.bayerpharma.com</a>
vericiguat (sGC stimulator)	Bayer HealthCare Pharmaceutical <i>Whippany, NJ</i>	worsening chronic heart failure	Phase II <a href="http://www.bayerpharma.com">www.bayerpharma.com</a>
<b>Xarelto</b> <sup>®</sup> rivaroxaban	Bayer HealthCare Pharmaceutical <i>Whippany, NJ</i> Janssen Research & Development <i>Raritan, NJ</i>	chronic heart failure	Phase III <a href="http://www.bayerpharma.com">www.bayerpharma.com</a> <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
XZK (Chinese red yeast rice extract)	Luye Pharmaceutical <i>Shandong, China</i> Beijing Peking University WBL Biotech <i>Beijing, China</i>	hyperlipidemia	Phase II <a href="http://www.wpu.com/cn/en">www.wpu.com/cn/en</a>

---

*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 June 4, 2014.** The medicines in this report include medicines being developed by U.S.-based companies conducting trials in the United States and abroad, PhRMA-member companies conducting trials in the United States and abroad, and foreign companies conducting clinical trials in the United States. 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 website.*

**A publication of PhRMA's Communications & Public Affairs Department (202) 835-3460**

[www.phrma.org](http://www.phrma.org) | [www.innovation.org](http://www.innovation.org) | [www.pparx.org](http://www.pparx.org)

Provided as a public service by PhRMA. Founded in 1958 as the Pharmaceutical Manufacturers Association.

Copyright © 2014 by the Pharmaceutical Research and Manufacturers of America. Permission to reprint is awarded if proper credit is given.

**Pharmaceutical Research and Manufacturers of America** • 950 F Street, NW, Washington, DC 20004

**Alzheimer's disease**—The most common form of dementia, characterized by progressive and chronic deterioration of cognitive functions, including memory, thinking and reasoning. Early manifestations include forgetfulness, impaired ability to focus, and changes in mood and personality. As the disease progresses, there is a loss of computational ability, in addition to word-finding problems and difficulty with ordinary activities. Ultimately, the disease leads to severe memory loss, complete disorientation, social withdrawal, loss of independence, and death.

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

**application submitted**—An application for marketing has been submitted to the U.S. Food and Drug Administration (FDA). The application can either be an NDA (new drug application) or a BLA (biologic license application).

**atrial fibrillation**—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.

**chronic obstructive pulmonary disease (COPD)**—A group of lung diseases, including chronic bronchitis and emphysema, in which there is a persistent disruption of airflow out of the lungs and eventual hypoxemia (low level of oxygen in the blood).

**cognitive disorders**—Disorders of the higher mental processes—including understanding, reasoning, knowledge, and intellectual capacity. A person with a cognitive disorder, such as Alzheimer's disease, does not process information correctly within the brain, resulting in impaired awareness and judgment, difficulty reasoning and focusing, loss of memory and abnormal mental capacity. People with cognitive disorders have problems acquiring, mentally organizing and responding to information, which results in an inability to function normally in everyday life situations.

**dementia**—The loss of mental ability that interferes with normal daily activities. It lasts more than six months, is not present at birth and is not associated with loss or altered consciousness. The natural decline of these functions with age is grossly exaggerated in dementia.

**depression**—Everyone occasionally feels blue or sad, but those feelings are usually short-lived and pass within a couple of days. Depression, however, interferes with daily life and causes pain for both the sufferers and those who care about them. Depression is a common but serious illness. Major depression and persistent depressive disorder are among the several forms of depressive disorders. Major depression causes severe symptoms that interfere with a person's ability to work, sleep, study, eat, and enjoy life. An episode can occur only once in a person's lifetime, but more often, a person has several episodes. Persistent depressive disorder causes a depressed mood that lasts for at least 2 years. A person diagnosed with persistent depressive disorder may have episodes of major depression along with periods of less severe symptoms, but symptoms must

last for 2 years. People with depressive illnesses do not all experience the same symptoms. The severity, frequency, and duration of symptoms vary depending on the individual and his or her particular illness. A few of the many signs and symptoms of depression are: persistent sad, anxious, or "empty" feelings; feelings of hopelessness or pessimism; fatigue and decreased energy; difficulty concentrating, remembering details, and making decisions; overeating, or appetite loss; and thoughts of suicide, or suicide attempts.

**diabetes**—A chronic disease in which the body does not produce or properly use insulin, a hormone that is needed to convert sugar, starches and other food into energy needed for daily life. Symptoms may include excessive thirst, hunger, urination and weight loss. The cause of diabetes continues to be a mystery, although both genetics and environmental factors such as obesity and lack of exercise appear to play roles. Type 1 diabetes results from the body's failure to produce insulin, which "unlocks" the cells of the body, allowing glucose to enter and fuel them. It is estimated that 5 percent to 10 percent of Americans who are diagnosed with diabetes have type 1, which requires insulin treatment. Type 2 diabetes results from insulin resistance (a condition in which the body fails to properly use insulin), combined with relative insulin deficiency. Most Americans who are diagnosed with diabetes have type 2, which in most cases can be controlled

**Phase 0**—First-in-human trials conducted in accordance with FDA's 2006 guidance on exploratory Investigational New Drug (IND) studies designed to speed development of promising drugs by establishing early whether the tested

if treated properly by a combination of dietary measures, weight loss, and oral medication.

**diabetic nephropathy**—Damage or disease to the kidney that can occur in people with diabetes. The kidneys have many tiny blood vessels that filter waste from the blood. High blood sugar from diabetes can destroy those blood vessels. Overtime, the kidney isn't able to do its job as well and may stop working completely, which is called kidney failure.

**Fast Track**—A process designed to facilitate the development and expedite the review of drugs to treat serious diseases and fill an unmet medical need. The status is assigned by the U.S. Food and Drug Administration (FDA). The purpose of this process is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious diseases. In general, determining factors for whether a drug receives Fast Track include whether the drug will affect factors such as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy that may be potentially superior to existing therapy. Once a drug receives Fast Track designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication ensures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.

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

**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.

**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.

**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.

**Hypothyroidism**—Also known as an underactive thyroid, is a condition where the thyroid gland doesn't produce enough of certain important hormones. Women, especially those older than age 60, are more likely to have hypothyroidism. The condition upsets the normal balance of chemical reactions in your body. It seldom causes symptoms in the early stages, but, if left untreated, it can lead to obesity, joint pain, infertility and heart disease.

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

**mild Alzheimer's disease**—A stage of Alzheimer's disease characterized by a series of changes in cognitive abilities that may include memory loss for recent events, difficulty with problem solving, changes in personality, difficulty organizing and expressing thoughts, getting lost or misplacing belongings. This is the stage at which the disease is often first diagnosed.

**moderate Alzheimer's disease**—A stage of Alzheimer's disease characterized by increased confusion, greater memory loss, significant changes in personality, and the need for assistance with basic daily activities. These changes are related to damage in areas of the brain that control language, reasoning, sensory processing, and conscious thinking. At this stage, patients may have problems recognizing family and friends, experience hallucinations, delusions, and paranoia, and may behave impulsively.

**Orphan Drug**—A drug to treat a disease that has a patient population of 200,000 or less in the United States, or a disease that has a patient population of more than 200,000 and a development cost that will not be recovered from sales in the United States.

**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.

compound behaves in humans as was anticipated from preclinical studies.

**Phase I**—Researchers test the drug in a small group of people, usually between 20 and 100 healthy adult volunteers, to evaluate its initial safety and tolerability profile, determine a safe dosage range, and identify potential side effects.

**Phase II**—The drug is given to volunteer patients, usually between 100 and 500, to determine whether the drug is effec-

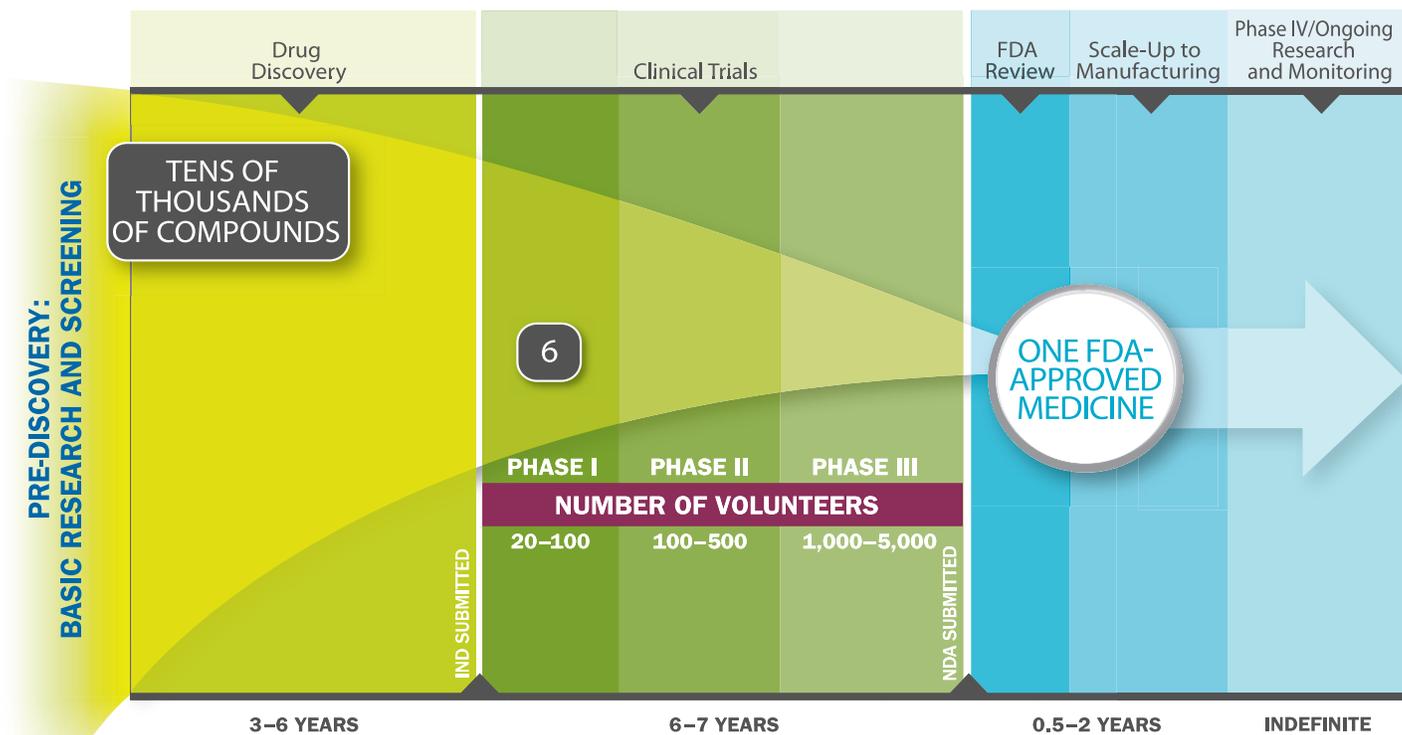
tive, identify an optimal dose, and to evaluate further its short-term safety.

**Phase III**—The drug is given to a larger, more diverse patient population, often involving between 1,000 and 5,000 patients (but sometimes many more thousands), to generate statistically significant evidence to confirm its safety and effectiveness. Phase III studies are the longest studies and usually take place in multiple sites around the world.

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

# The Drug Discovery, Development and Approval Process

Developing a new medicine takes an average of 10-15 years;  
Tens of thousands of compounds are screened, only 1 is 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. Tens of thousands of compounds may be screened early in development, but only one ultimately receives approval. Even medicines that reach clinical trials have only a 16 percent chance of being approved.

On average, it costs a company \$1.2 billion, including the cost of failures, 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. More recent studies estimate the cost to be even higher.

Once a new compound has been identified in the laboratory, medicines are usually 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 com-

pany 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**—Researchers test the drug in a small group of people, usually between 20 and 100 healthy adult volunteers, to evaluate its initial safety and tolerability profile, determine a safe dosage range, and identify potential side effects.

**Clinical Trials, Phase II**—The drug is given to volunteer patients, usually between 100 and 500, to see if it is effective, identify an optimal dose, and to further evaluate its short-term safety.

**Clinical Trials, Phase III**—The drug is given to a larger, more diverse patient population, often involving between 1,000 and 5,000 patients

(but sometime many more thousands), to generate statistically significant evidence to confirm its safety and effectiveness. They are the longest studies, and usually take place in multiple sites around the world.

**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.

**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 \$51.1 billion in research and development in 2013.