



Respiratory – Pulmonary System

The main function of the respiratory system (also known as the pulmonary system) is to supply the body with oxygen and rid it of carbon dioxide. This process also removes metabolic wastes and maintains the pH balances of the body. The organs involved are the airways, lungs, and muscles that mediation the movement of air into and out of the body. When you breathe, air comes in through the mouth and nose. It passes through the larynx, also known as the voice box, and enters the chest cavity through the trachea. The trachea then splits into two tubes called bronchi, each of which leads into a lung. The airways become progressively smaller and at the end are small sacs known as alveoli, which are surrounded by capillaries. The oxygen from the air moves into the alveoli. Carbon dioxide moves through the same path in the opposite direction when you exhale.

Asthma

Asthma is a disease that affects the tubes (airways) that bring air to and from the lungs. When the airways become inflamed, they swell up, making it difficult to breathe. The causes of asthma are unclear, but heredity and external factors play a role. Allergens (pollen, dust, and animal dander), lung irritants (cigarette smoke, pollution, and cold air), and certain medications can bring about an asthma attack, though there are many other factors that may affect the lungs as well. Asthma treatments seek to prevent inflammation of the airways and are characterized as long term (daily medications) or quick relief (taken when the attack is already occurring, to open up the airways and halt the attack). Asthma ranks among the most common chronic conditions in the United States and the National Institutes of Health estimates that in 1995, 14.9 million persons were affected, causing 1.5 million emergency department visits, about 500,000 hospitalizations, and over 5,500 deaths.

	COMPANY	PRODUCT	PHASE
Asthma	AEROVANCE, Inc.	Aerovant / AER 001	II
	Aradigm Corp.	AERx HCQ / Aerosolized hydrochloroquine	II
	Gilead Sciences, Inc.	Corus 1030 (lidocaine)	II
	Theravance, Inc.	GSK159797 / TD-3327	II
	Theravance, Inc.	GSK159802	II
	Theravance, Inc.	GSK 597901	II
Respiratory Diseases (General)	Theravance, Inc.	GSK 678007	II
Asthma	Dynavax Technologies Corp.	Inhaled 1018 ISS	II
	Inverseon, Inc.	INV102	II
	MAP Pharmaceuticals, Inc.	MAP0010 / unit dose budesonide (UDB)	II
	PDL BioPharma, Inc.	Zenapax (daclizumab)	II
	Genentech, Inc.	Xolair (omalizumab)	III
	Dey L.P.	Cromolyn Sodium Inhalation Solution	M
	Dey L.P.	Metaproterenol Sulfate Inhalation Solution	M
	BioMarin Pharmaceutical, Inc.	Orapred (prednisolone sodium phosphate oral solution)	M
Respiratory Diseases (General)	Novartis AG	Streptopur	M
Asthma	Impax Laboratories, Inc.	Terbutaline Sulfate Tablets	M
	Genentech, Inc.	Xolair (omalizumab)	M

Bronchospasm

Bronchospasm is characterized by difficulty breathing due to the sudden constriction of the bronchioles in the lungs. The constriction and inflammation causes the airways to narrow and

mucus production to increase, reducing the amount of oxygen available to the body. This causes breathlessness, coughing and hypoxia. Bronchospasm usually accompanies asthma, chronic bronchitis and anaphylaxis.

COMPANY	PRODUCT	PHASE	
Dey L.P.	Ipratropium Bromide Inhalation Solution	M	Bronchospasm
Dey L.P.	Metaproterenol Sulfate Inhalation Solution	M	
Dey L.P.	AccuNeb (albuterol sulfate) Inhalation Solution	M	

Chronic Obstructive Pulmonary Disease (COPD)/ Bronchitis

Breathing is always difficult for the 11.2 million Americans affected by COPD because their airways, the tubes that bring air to and from the lungs, are damaged. In normal breathing, the air sacs at the end of the airways inflate and deflate again when they exhale. A patient with COPD is affected in four main ways: the air sacs are less elastic, so they do not inflate optimally; the walls between the air sacs break down, resulting in fewer, less efficient air sacs; the airways become inflamed and swollen; and more mucus is produced, which blocks the airways further.

There are two main types of COPD: emphysema and chronic bronchitis. Emphysema is a result of the destruction of the walls between the air sacs, while chronic bronchitis can be blamed on inflamed airways and increased mucus production. Most people with COPD generally suffer from both emphysema and chronic bronchitis.

COMPANY	PRODUCT	PHASE	
Theravance, Inc.	642444	II	Chronic Obstructive Pulmonary Disease
Theravance, Inc.	GSK159797 / TD-3327	II	
Theravance, Inc.	GSK159802	II	
Theravance, Inc.	GSK 597901	II	
AEROVANCE, Inc.	Pulmolytic / AER 002	II	
Novartis AG	TOBI	II	
Dey L.P.	DuoNeb (ipratropium bromide and albuterol sulfate) Inhalation Solution	M	

Cystic Fibrosis (CF)

According to the NIH, about 30,000 people in the United States are affected by cystic fibrosis, a genetic disease that affects cells' ability to regulate how much salt they bring in and store. One of the characteristics of CF is that sweat is saltier than normal—in fact, kissing a child and tasting their "salty sweat" is often how parents first suspect that their child may have CF.

In patients with CF, the normally thin and slippery mucus naturally produced in the body is thick and sticky, which can cause several problems. First, the pancreas may become blocked so that it can't produce the enzymes needed to digest and absorb food. The liver is also obstructed, which can result in permanent liver damage. The most common and dangerous complication, however, involves the lungs. The thick mucus clogs the lungs, making it difficult to breathe, and puts the patient at risk for life-threatening lung infections. Treatments seek to reduce the thickness and amount of mucus in the body, especially the lungs.

	COMPANY	PRODUCT	PHASE
Cystic Fibrosis	AEROVANCE, Inc.	Aerolytic/ AER 002	II
	Gilead Sciences, Inc.	Corus 1020 / Cayston (aztreonam)	III
	Nektar Therapeutics	TIP (Tobramycin Powder for Inhalation)	III
	Novartis AG	Tobi (Tobramycin Powder for Inhalation)	III
	Genentech, Inc.	Pulmozyme (dornase alfa)	M
Mucolytic Agent	Dey L.P.	Sterile Acetylcysteine Solutions	M
Cystic Fibrosis	Novartis AG	Tobi (Tobramycin)	M

Emphysema

Emphysema is a chronic lung disease most often caused by prolonged exposure to toxic chemicals and tobacco smoke. It is characterized by the loss of elasticity of the lung tissue, destruction of structures supporting the alveoli, and destruction of capillaries feeding the alveoli. As a result, the small airways collapse during expiration and air gets trapped in the lungs. Symptoms include shortness of breath on exertion, hyperventilation (to get more oxygen into the lungs), and an expanded chest.

	COMPANY	PRODUCT	PHASE
Emphysema	Arriva Pharmaceuticals, Inc	Recombinant alpha 1-antitrypsin / rAAT	II

Nasal Dryness

After exposure to certain conditions (such as air conditioning, coldness, and dry weather) our skin becomes dry and requires moisture to restore it back to its normal state. Treatments such as lotions for the skin, and drops for the eyes and nose are helpful in adding much-needed moisture.

	COMPANY	PRODUCT	PHASE
Nasal Dryness	Parnell Pharmaceuticals, Inc.	Pretz	M

Pulmonary Fibrosis

Though this term has fallen out of favor in recent years, pulmonary fibrosis refers to the formation of excess fibrous connective tissue in an organ or tissue as part of a reparative or reactive process. Idiopathic pulmonary fibrosis involves the scarring of the lung and gradually air sacs become replaced with fibrotic tissues. This affects the lungs' ability to move oxygen into the bloodstream. Symptoms include shortness of breath, chronic dry, hacking cough, fatigue and weakness, discomfort in the chest, loss of appetite, and rapid weight loss.

Currently in the United States there are over 200,000 patients with pulmonary fibrosis, though the number is probably much higher due to misdiagnosis. Patients are usually in their 40s and 50s when they are diagnosed, but all ages can develop the disease. Though no specific cause has been identified, evidence indicates that most patients have a genetic predisposition to the condition. Environmental and occupational pollutants, cigarette smoke, diseases, medications, and radiation seem to exacerbate the disease. There are currently no effective treatments or cures.

COMPANY	PRODUCT	PHASE	
CoTherix, Inc.	Ventavis (iloprost)	II	Pulmonary Fibrosis
InterMune, Inc.	Actimmune (interferon gamma-1b)	III	
InterMune, Inc.	Pirfenidone	III	

Pulmonary Embolism

Pulmonary embolism is the blockage of an artery in the lungs by a blood clot, fat, air or tumor cells clumped together. The most common form is a blood clot that originated as a deep vein thrombus and traveled through the arteries into the lungs. Most patients are diagnosed through pulmonary angiopathy and CT scans. Symptoms include difficulty breathing, pain during breathing, and circulatory instability. Treatment generally involves an anticoagulant medication and potentially surgery to remove the clot. The American Heart Association estimates that approximately 600,000 Americans develop pulmonary embolisms each year.

COMPANY	PRODUCT	PHASE	
Genentech, Inc.	Activase (alteplase)	M	Pulmonary Embolism

Pulmonary Hypertension

Pulmonary hypertension is an increase in blood pressure in the pulmonary artery. It can be a severe disease marked by decreased exercise tolerance and right-sided heart failure. Symptoms include shortness of breath, fatigue, cough, angina, fainting, and edema. The most common cause of pulmonary hypertension is left heart failure due to a malfunction of the left ventricle, though HIV, scleroderma, and other autoimmune disorders can also lead to this disease. Pulmonary embolism can also be a factor. When no cause is found, the disease is termed idiopathic pulmonary arterial hypertension. Treatments vary based on the cause.

COMPANY	PRODUCT	PHASE	
CoTherix, Inc.	Ventavis and Sildenafil	III	Pulmonary Hypertension
CoTherix, Inc.	Ventavis (iloprost)	M	
CoTherix, Inc.	Ventavis (iloprost) and Tracleer (bosentan)	M	
Genentech, Inc.	Tracleer (bosentan)	PM	

Respiratory Distress Syndrome

Respiratory distress syndrome is a serious reaction to injuries of the lung resulting in increased permeability pulmonary edema. It is characterized by inflammation of the lung leading to impaired gas exchange and multiple organ failure. The condition is life threatening and often fatal, requiring mechanical ventilation and admission to an intensive care unit.

COMPANY	PRODUCT	PHASE	
Dey L.P.	Curosurf (poractant alfa) Intratracheal Suspension	M	Respiratory Distress Syndrome

