

## Overview

For investors in pharmaceutical and biotech companies, rigorous monitoring of drug pipelines is essential. No milestone is more influential than the FDA approval decision date, frequently called the PDUFA date (from Prescription Drug User Fee Act).

This Revere Report features **companies with expected FDA approval decision dates in the next three months**. To provide further insights into **each drug candidate's likelihood of approval and competitive landscape**, the FDA Approval Decisions Report includes **key data based on Revere's patented classification system and proprietary pipeline database** – specifically, whether each drug candidate:

- utilizes a mechanism of action already approved by the FDA in other drugs
- faces two or fewer alternative drugs with the same mechanism of action for the same indication
- would be the first or second FDA approved drug for the company

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### **Notes:**

- a) Some expected PDUFA (Prescription Drug User Fee Act) dates are Revere estimates based on NDA (New Drug Approval) submission dates. Companies are not obligated to disclose NDA submission dates or PDUFA dates, and the FDA may change its approval decision date without prior notice.
- b) Drugs developed by private firms or by companies not traded publicly in the U.S. are excluded from this analysis.

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## 1. June Approval Results/Updates

Company (Symbol)	Drug Candidate	Indication	Previous Expected PDUFA Date*	Primary Mechanism of Action (PMOA)	Approval Results/Update
<b>BioMarin Pharmaceutical (BMRN)</b>	Orapred ODT (Prednisolone Sodium Phosphate)	Severe Asthma	<b>6/1/2006</b>	Steroidal Anti-Inflammatory Drugs (SAID)	<b>Approved</b> by FDA on 6/1/2006
<b>Merck &amp; Co., Inc. (MRK) / sanofi-aventis (SNY)</b>	Gardasil	Human Papillomavirus (HPV) Vaccine, Cervical Cancer Vaccine	<b>6/8/2006</b>	Papillomavirus Vaccines	<b>Approved</b> by FDA on 6/8/2006
<b>GlaxoSmithKline plc (GSK) / POZEN Inc. (POZN)</b>	Trexima (Naproxen/ Sumatriptan)	First-Line Therapy for Migraine Headaches	6/8/2006	Non-Steroidal Anti-Inflammatory Drugs (NSAID)/ Selective Serotonin Receptor Agonists	<b>Approvable Letter</b> received on 6/9/2006
<b>GlaxoSmithKline plc (GSK)</b>	Hycamtin (Topotecan Hydrochloride)	Stage IV-B, Recurrent or Persistent Cervical Cancer not Amenable to Curative Treatment with Surgery and/or Radiation Therapy	6/15/2006	Topoisomerase I Inhibitors	<b>Approved</b> by FDA on 6/15/2006
<b>Endo Pharmaceuticals (ENDP) / Penwest Pharmaceuticals (PPCO)</b>	Opana ER (Oxymorphone Hydrochloride Extended-Release)	Moderate-to-Severe Pain	<b>6/22/2006</b>	Opioids	<b>Approved</b> by FDA on 6/22/2006
<b>Endo Pharmaceuticals (ENDP)</b>	Opana (Oxymorphone Hydrochloride Immediate-Release)	Moderate-to-Severe Pain	<b>6/22/2006</b>	Opioids	<b>Approved</b> by FDA on 6/22/2006
<b>Johnson &amp; Johnson (JNJ)</b>	Prezista (Darunavir)	Human Immunodeficiency Virus (HIV) in Antiretroviral Treatment-Experienced Adults	<b>6/23/2006</b>	Protease Inhibitors	<b>Approved</b> by FDA on 6/23/2006
<b>Biogen Idec Inc (BIIB) / Elan Corporation, plc (ELN)</b>	Tysabri (Natalizumab)	Relapsing Forms of Multiple Sclerosis (MS)	<b>6/28/2006</b>	Alpha 4 Integrin Inhibitors	<b>Approved</b> by FDA on 6/5/2006
<b>Novartis AG (NVS)</b>	Exelon (Rivastigmine Tartrate)	Mild to Moderate Dementia Associated with Parkinson's Disease	May 2006	Acetylcholine-sterase Inhibitors	<b>Approved</b> by FDA on 6/27/2006

Company (Symbol)	Drug Candidate	Indication	Previous Expected PDUFA Date*	Primary Mechanism of Action (PMOA)	Approval Results/Update
<b>Schering-Plough Corp. (SGP)</b>	Noxafil (Posaconazole)	Prophylaxis of Serious Invasive Fungal Infections in High Risk Patients	<i>6/22/2006</i>	Imidazoles	Result Pending
<b>Bristol Myers Squibb Co. (BMY)</b>	Sprycel (Dasatinib)	Chronic Myelogenous Leukemia (CML)	<b>6/28/2006</b>	Tyrosine Kinase Inhibitors	Result Pending
<b>Celgene Corporation (CELG)</b>	Revlimid (Lenalidomide)	Relapsed/ Refractory Multiple Myeloma	<b>6/30/2006</b>	Immunomodulatory Agents	Result Pending
<b>Roche Holding Ltd. (RHHBY) / Novartis AG (NVS) / Genentech, Inc. (DNA)</b>	Lucentis (Ranibizumab)	Wet Age-Related Macular Degeneration (AMD)	<b>6/30/2006</b>	Vascular Endothelial Growth Factor Inhibitors (VEGF)	Result Pending
<b>Cephalon, Inc. (CEPH)</b>	Cima Labs OraVescent Fentanyl	Management of Breakthrough Pain in Patients with Cancer	<b>6/30/2006</b>	Opioids	Result Pending
<b>Cellegy Pharmaceuticals, Inc. (CLGY)</b>	Cellegesic (Nitroglycerin)	Pain Associated with Anal Fissures/ Treatment of Anal Fissures	<i>6/30/2006</i>	Vasodilatory Agents	Result Pending
<b>sanofi-aventis (SNY)</b>	Multaq (Dronedarone)	Atrial Fibrillation	<i>June 2006</i>	Sodium Channel Blocking Agents/ Potassium Channel Blocking Agents	Result Pending
<b>Eli Lilly &amp; Co. (LLY)</b>	Arxxant (Ruboxistaurin Mesylate)	Diabetic Retinopathy	<i>June 2006</i>	PKC-beta Inhibitors	Result Pending
<b>Sanofi-aventis (SNY)</b>	Pentacel	Combination Vaccine for Diphtheria, Tetanus, Pertussis, Polio, Haemophilus influenzae type b (Hib) in Children	<i>5/25/2006</i>	Bacterial/Viral Vaccines	Result Pending
<b>King Pharmaceuticals (KG) / Wyeth (WYE)</b>	Altace (Ramipril)	Delaying the Progression of Chronic Kidney Disease In Hypertensive, Non-Diabetic Patients	<i>5/22/2006</i>	Angiotensin Converting Enzyme Inhibitors (ACE Inhibitors)	Result Pending

\* Dates in **bold** indicate that Revere has confirmed directly with the company or indirectly through company filings and press releases. Dates in *italics* indicate Revere estimates based on NDA (New Drug Approval) submission dates.






















## 2. Companies with Expected PDUFA Dates in the Next Three Months

July	August	September
AstraZeneca PLC (AZN)	Abbott Laboratories (ABT)	Amgen, Inc. (AMGN)
Barrier Therapeutics, Inc. (BTRX)	Cambridge Antibody Tech. Group plc (CATG)	AstraZeneca PLC (AZN)
Encysive Pharmaceuticals, Inc. (ENCY)	Cephalon, Inc. (CEPH)	Connetics Corporation (CNCT)
<b>Johnson &amp; Johnson (JNJ) [2]</b>	Enzon Pharmaceuticals, Inc. (ENZN)	Eisai Co., Ltd (ESALY)
MedImmune, Inc. (MEDI)	Genentech, Inc. (DNA)	GlaxoSmithKline plc (GSK)
	Neurochem Inc. (NRMX)	Johnson & Johnson (JNJ)
	Roche Holding Ltd. (RHHBY)	Labopharm Inc. (DDSS)
	Salix Pharmaceuticals Ltd (SLXP)	Oscient Pharmaceuticals Corp (OSCI)
	sanofi-aventis (SNY)	Pharmion Corporation (PHRM)
	Shire plc (SHPGY)	
<b>Total Companies = 5</b>	<b>Total Companies = 10</b>	<b>Total Companies = 9</b>

### Notes:

- Some drug candidates are filed jointly by two companies.
- Companies with multiple drug candidates in the same month are shown in **bold type** with the number of drug candidates in brackets [ ].

## 3. Expected PDUFA Dates by Sector\*

July	August	September
<b>I *Healthcare</b>  <b>Biopharmaceuticals [6]</b>  <b>Cardiovascular System [1]</b>  <b>Dermatology [2]</b>  <b>Infectious Diseases [1]</b>  <b>Pain Management [1]</b>  <b>Respiratory System [1]</b>	<b>I *Healthcare</b>  <b>Biopharmaceuticals [7]</b>  <b>Digestive System [1]</b>  <b>Endocrinology/Metabolism [1]</b>  <b>Immunology [1]</b>  <b>Musculoskeletal System [1]</b>  <b>Neurology [1]</b>  <b>Oncology [2]</b>	<b>I *Healthcare</b>  <b>Biopharmaceuticals [9]</b>  <b>Cardiovascular System [1]</b>  <b>Dermatology [1]</b>  <b>Hematology [1]</b>  <b>Infectious Diseases [2]</b>  <b>Neurology [2]</b>  <b>Oncology [1]</b>  <b>Pain Management [1]</b>
<b>Total PDUFA Dates = 6</b>	<b>Total PDUFA Dates = 7</b>	<b>Total PDUFA Dates = 9</b>

\* Based on Revere's [proprietary classification system](#).

## 4. July Drug Candidates

Company (Symbol)	Drug Candidate	Indication	Expected PDUFA Date*	Primary Mechanism of Action (PMOA)	Proven PMOA?	If Approved, Drug Will Likely Face Two or Fewer Alternatives in Same Drug Class for Same Indication?	1st or 2nd FDA Approved Drug of the Company?
<b>Johnson &amp; Johnson (JNJ)</b>	Remicade (Infliximab)	Moderate to Severe Plaque Psoriasis	<i>7/07/2006</i>	TNF-Alpha Antagonists	Yes	Yes—Enbrel (AMGN), Humira(ABT)	No
<b>MedImmune Inc. (MEDI)</b>	Cold Adapted Influenza Vaccine-Trivalent (CAIV-T)	Influenza (Flu) Vaccine in Healthy Individuals 5 to 49 Years of Age	<i>7/19/2006</i>	Influenza (Flu) Vaccine	Yes	No—Multiple	No
<b>AstraZeneca Inc. (AZN)</b>	Symbicort pMDI (Formoterol/ Budesonide)	Maintenance Treatment of Asthma	<i>7/24/2006</i>	Beta Adrenergic Receptor Agonists/Steroidal Anti-Inflammatory Drugs (SAID)	Yes	No—Multiple	No
<b>Encysive Pharmaceuticals, Inc. (ENCY)</b>	Thelin (Sitaxsentan)	Pulmonary Arterial Hypertension (PAH)	<b>7/24/2006</b>	Endothelin Receptor Antagonists	No	Yes—Ambrisentan (MYOG)	Yes
<b>Barrier Therapeutics, Inc. (BTRX)</b>	Sebazole (Ketoconazole)	Seborrheic Dermatitis	<i>July 2006</i>	Imidazoles	Yes	Yes—Loprox (MRX), Nizoral (JNJ)	No
<b>Johnson &amp; Johnson (JNJ)</b>	TetraPeel	Local Anesthetic Prior to Surgery	<i>July 2006</i>	Opioids	Yes	Yes—Only Drug Candidate with This PMOA for This Indication	No

\* Dates in **bold** indicate that Revere has confirmed directly with the company or indirectly through company filings and press releases. Dates in *italics* indicate Revere estimates based on NDA (New Drug Approval) submission dates.

## 5. August Drug Candidates

Company (Symbol)	Drug Candidate	Indication	Expected PDUFA Date*	Primary Mechanism of Action (PMOA)	Proven PMOA?	If Approved, Drug Will Likely Face Two or Fewer Alternatives in Same Drug Class for Same Indication?	1st or 2nd FDA Approved Drug of the Company?
<b>Salix Pharmaceuticals Ltd (SLXP)</b>	MoviPrep (formerly NRL944)	Bowel Cleansing Prior To Colonoscopy, Intestinal Surgery and Barium Enema X-Ray Examinations	<b>8/2/2006</b>	Hyperosmotic Agents	Yes	Yes—Colyte (SWTZY), LiquiPrep (EZEM)	No
<b>sanofi-aventis (SNY) / Enzon Pharmaceuticals, Inc. (ENZN)</b>	Oncaspar (PEG L-Asparaginase)	First-Line Therapy for Acute Lymphoblastic Leukemia (ALL)	<i>8/3/2006</i>	Asparaginases	Yes	Yes—Only Drug Candidate with This PMOA for This Indication	No

Company (Symbol)	Drug Candidate	Indication	Expected PDUFA Date*	Primary Mechanism of Action (PMOA)	Proven PMOA?	If Approved, Drug Will Likely Face Two or Fewer Alternatives in Same Drug Class for Same Indication?	1st or 2nd FDA Approved Drug of the Company?
Abbott Laboratories (ABT) / Cambridge Antibody Tech. Group plc (CATG)	Humira (Adalimumab)	Ankylosing Spondylitis	<i>8/4/2006</i>	TNF-Alpha Antagonists	Yes	Yes—Enbrel (AMGN, WYE), Remicade (JNJ)	No
Neurochem Inc. (NRMX)	Fibrillex	Amyloid A Amyloidosis	<b>8/11/2006</b>	Glycosaminoglycan (GAG) Mimetic Agents	No	Yes—Only Drug Candidate with This PMOA for This Indication	Yes
Genentech, Inc. (DNA) / Roche Holding Ltd. (RHHBY)	Herceptin (Trastuzumab)	Early Stage, HER2-Positive Breast Cancer	<i>8/15/2006</i>	Monoclonal Antibodies	Yes	Yes—Only Drug Candidate with This PMOA for This Indication	No
Cephalon, Inc. (CEPH)	Sparlon (Modafinil)	Attention Deficit Hyperactivity Disorder (ADHD) In Children and Adolescents between 6 and 17	<b>8/22/2006</b>	Alpha Adrenergic Receptor Agonists	Yes	Yes—SPD 465, SPD 503 (SHPGY)	No
Shire plc (SHPGY)	Elaprase (Idursulfase)	Hunter Syndrome (Mucopolysaccharidosis II)	<b>8/24/2006</b>	Enzyme Replacement Therapy	Yes	Yes—Only Drug Candidate with This PMOA for This Indication	No

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## 6. September Drug Candidate

Company (Symbol)	Drug Candidate	Indication	Expected PDUFA Date*	Primary Mechanism of Action (PMOA)	Proven PMOA?	If Approved, Drug Will Likely Face Two or Fewer Alternatives in Same Drug Class for Same Indication?	1st or 2 <sup>nd</sup> FDA Approved Drug of the Company?
AstraZeneca PLC (AZN)	Metoprolol Succinate/Hydrochlorothiazide Combination Therapy	Hypertension	<i>9/1/2006</i>	Beta Blockers / Thiazide Diuretic Agents	No	Yes—Only Drug Candidate with This PMOA for This Indication	No
Eisai Co., Ltd (ESALY)	Inovelon (Rufinamide)	Pediatric Epilepsy, Adjunctive Therapy for Partial-Onset Seizures in Adults and Adolescents	<i>9/14/2006</i>	Sodium Channel Blocking Agents	Yes	Yes—Lamictal (GSK), Trileptal (NVS)	No

Company (Symbol)	Drug Candidate	Indication	Expected PDUFA Date*	Primary Mechanism of Action (PMOA)	Proven PMOA?	If Approved, Drug Will Likely Face Two or Fewer Alternatives in Same Drug Class for Same Indication?	1st or 2nd FDA Approved Drug of the Company?
Connetics Corporation (CNCT)	Desilux (Desonide)	Atopic Dermatitis (Eczema)	<b>9/21/2006</b>	Steroidal Anti-Inflammatory Drugs (SAID)	Yes	Yes—Synalar (MRX), Cortizone 5/10 (PFE)	No
Oscient Pharmaceuticals Corporation (OSCI)	FACTIVE (Gemifloxacin Mesylate)	5 Day Therapy for Mild to Moderate Community-Acquired Pneumonia	<b>9/21/2006</b>	Quinolones/Fluoroquinolones	Yes	No—Multiple	Yes
Labopharm Inc. (DDSS)	Tramadol Once-Daily	Moderate to Severe Pain	<b>9/28/2006</b>	Opioids	Yes	No—Multiple	Yes
Pharmion Corporation (PHRM)	Vidaza (Azacitidine)	Myelodysplastic Syndromes (MDS)	<b>9/29/2006</b>	Pyrimidine Analogs	Yes	Yes—Dacogen (MOGN, SUPG)	Yes
Amgen, Inc. (AMGN)	Panitumumab	Metastatic Colon Cancer in Patients Who Have Failed Previous Chemotherapy	<b>9/29/2006</b>	Monoclonal Antibodies	Yes	Yes—Erbix (BMX, IMCL), Avastin (DNA, RHHBY)	No
Johnson & Johnson (JNJ)	Paliperidone ER OROS	Schizophrenia	<b>9/29/2006</b>	Serotonin /Dopamine Receptor Blocking Agents	Yes	No—Multiple	No
GlaxoSmithKline plc (GSK)	Altanax (Retapamulin)	Uncomplicated Skin and Skin Structure Infections due to Susceptible Strains of S. aureus and S. pyogenes	<i>September 2006</i>	Pleuromutilins	No	Yes—Only Drug Candidate with This PMOA for This Indication	No

\* Dates in **bold** indicate that Revere has confirmed directly with the company or indirectly through company filings and press releases. Dates in *italics* indicate Revere estimates based on NDA (New Drug Approval) submission dates.

## 7. Price and Financial Info

Data as of June 26, 2006

Company (Symbol)	Last Price	Market Cap. (M)	30-Day Avg. Volume	Price/Book	Total Debt/Equity (MRQ)	Cash & Equivalents + Short-Term Investments (MRQ) (M)	1-Year Return	Relative Performance vs. Revere Biopharm Index	Institutional Holdings (Subscribers Only)	Options Available ?
<b>July</b> AstraZeneca PLC (AZN)	56.93	89,836	1,174,770	6.58	0.086	6,065	37.90%	34.80%	●	YES
Barrier Therapeutics, Inc. (BTRX)	5.61	135	105,278	2.03	0.010	68	-64.17%	-67.27%	●	NO
Encysive Pharmaceuticals, Inc. (ENCY)	6.79	402	3,389,395	N/A	N/A	101	-39.85%	-42.95%	●	YES

	Johnson & Johnson (JNJ)	60.21	178,283	8,706,400	4.31	0.068	17,185	-9.29%	-12.39%	●	YES
	MedImmune, Inc. (MEDI)	27.08	6,736	3,395,034	3.86	0.300	854	-1.97%	-5.07%	●	YES
August	Abbott Laboratories (ABT)	42.03	64,147	4,173,396	4.41	0.44	2,405	-15.00%	-18.10%	●	YES
	Cambridge Antibody Tech. Group plc (CATG)	24.01	1,272	35,693	3.67	0.00	303	93.02%	89.93%	●	NO
	Cephalon, Inc. (CEPH)	52.78	3,206	1,382,064	3.48	2.24	541	39.68%	36.59%	●	YES
	Enzon Pharmaceuticals, Inc. (ENZN)	7.40	324	953,301	N/A	N/A	154	15.83%	12.74%	●	YES
	Genentech, Inc. (DNA)	79.11	83,352	3,153,464	10.35	0.27	2,284	-3.04%	-6.13%	●	YES
	Neurochem Inc. (NRMX)	10.59	409	98,009	10.59	0.00	54	3.36%	0.27%	●	YES
	Roche Holding Ltd. (RHHBY)	79.35	136,889	N/A	5.05	0.28	16,265	26.06%	22.97%	●	NO
	Salix Pharmaceuticals Ltd. (SLXP)	12.06	561	591,881	2.20	0.00	59	-30.58%	-33.67%	●	YES
	sanofi-aventis (SNY)	47.01	131,751	757,252	2.32	0.00	N/A	12.67%	9.58%	●	YES
	Shire plc (SHPGY)	42.73	7,131	568,821	3.72	0.00	844	25.00%	21.91%	●	YES
September	Amgen, Inc. (AMGN)	64.88	76,508	8,309,632	4.25	0.52	5,047	4.75%	1.65%	●	YES
	AstraZeneca PLC (AZN)	56.93	89,836	1,174,770	6.58	0.09	6,065	37.90%	34.80%	●	YES
	Connetics Corporation (CNCT)	12.00	411	399,471	3.74	0.00	244	-36.93%	-40.03%	●	YES
	Eisai Co., Ltd (ESALY)	43.05	12,305	N/A	2.91	0.00	1,342	30.06%	26.96%	●	NO
	GlaxoSmithKline plc (GSK)	53.98	156,740	1,209,686	9.66	0.70	10,514	9.04%	5.94%	●	YES
	Johnson & Johnson (JNJ)	60.21	178,283	8,706,400	4.31	0.07	17,185	-9.29%	-12.39%	●	YES
	Labopharm Inc. (DDSS)	7.73	438	67,693	N/A	N/A	22	N/A	N/A	●	NO
	Oscient Pharmaceuticals Corp (OSCI)	0.97	93	284,649	9.70	18.11	52	-62.91%	-66.01%	●	NO
Pharmion Corporation (PHRM)	16.11	516	527,419	1.56	0.00	185	-32.13%	-35.23%	●	YES	