

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. February Approval Results/Updates

Company (Symbol)	Drug Candidate	Indication	Previous Expected PDUFA Date*	Primary Mechanism of Action (PMOA)	Approval Results/Update
Merck & Co., Inc. (MRK)	Rotateq	Rotavirus Gastroenteritis Vaccine	2/6/2006	Rotavirus Vaccine	Approved by FDA on 2/3/2006
Biogen Idec Inc. (BIIB) / Genentech, Inc. (DNA) / Roche Holding Ltd. (RHHBY)	Rituxan (Rituximab)	Front-Line Treatment of Intermediate/High-Grade Non-Hodgkin's Lymphoma (NHL)	2/13/2006	Monoclonal Antibodies	Approved by FDA on 2/10/2006
Barrier Therapeutics, Inc. (BTRX)	Vusion (Miconazole)	Infants with Candida-Associated Diaper Dermatitis	February 2006	Imidazoles	Approved by FDA on 2/16/2006
Pfizer Inc. (PFE)	Eraxis (Anidulafungin)	Invasive Candidiasis/ Candidemia	2/20/2006	Echinocandins	Approved by FDA on 2/17/2006
Santarus, Inc. (SNTS)	Zegerid Capsule (Omeprazole)	GERD, Erosive Esophagitis (EE), Duodenal Ulcer, Gastric Ulcers, Prevention of Upper GI Bleeding in Critically Ill Patients	2/27/2006	Proton Pump Inhibitors	Approved by FDA 2/27/2006
Bristol Myers Squibb Co. (BMY) / Mylan Laboratories Inc. (MYL) / Watson Pharmaceuticals, Inc. (WPI)	Emsam (Selegiline Transdermal System)	Major Depressive Disorder (MDD)	2/27/2006	Monoamine Oxidase (MAO) Inhibitors	Result Pending
Merck & Co. (MRK)	Zostavax	Herpes Zoster (Shingles) Vaccine, Postherpetic Neuralgia (PHN), Reduction Of Acute And Chronic Shingles-Associated Pain In Adults	2/27/2006	Herpes Zoster (Shingles) Vaccine	PDUFA extended for 3 months to 5/25/2006
BioDelivery Sciences International, Inc. (BDSI) / Accentia Biopharmaceuticals, Inc (ABPI)	Emezine (Buccal Prochlorperazine Maleate)	Severe Nausea/Vomiting	2/28/2006	Dopamine Receptor Blocking Agents	Result Pending
Biogen Idec Inc. (BIIB) / Genentech, Inc. (DNA) / Roche Holding Ltd. (RHHBY)	Rituxan (Rituximab)	Moderate-To-Severe Rheumatoid Arthritis	2/28/2006	Monoclonal Antibodies	Result Pending
sanofi-aventis (SNY)	Acomplia (Rimonabant)	Treatment Of Obesity, Smoking Cessation	March 2006	Cannabinoid Receptor Antagonists	Approvable Letter received on 2/17/2006 for obesity treatment; Non-Approvable Letter received for smoking cessation on 2/17/2006.

* 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

March	April	May
Amgen, Inc. (AMGN)	Alkermes, Inc. (ALKS)	Bristol Myers Squibb Co. (BMY)
Biogen Idec Inc. (BIIB)	Cephalon, Inc. (CEPH) [3]	CollaGenex Pharmaceutical, Inc (CGPI)
Bristol Myers Squibb Co. (BMY)	Discovery Laboratories (DISCO)	DOV Pharmaceutical, Inc. (DOVP)
Cubist Pharmaceuticals (CBST)	Genzyme Corporation (GENZ)	Johnson & Johnson (JNJ)
Elan Corporation, plc (ELN)	Pfizer Inc. (PFE)	King Pharmaceuticals (KG)
Encysive Pharmaceuticals, Inc. (ENCY)	Salix Pharmaceuticals Ltd (SLXP)	Merck & Co., Inc. (MRK)
ImClone Systems Inc. (IMCL)	sanofi-aventis (SNY)	MGI Pharma, Inc. (MOGN)
NPS Pharmaceuticals, Inc. (NPSP)		Neurocrine Biosciences, Inc. (NBIX)
Salix Pharmaceuticals Ltd (SLXP)		Pfizer Inc. (PFE) [2]
Santarus, Inc. (SNTS)		sanofi-aventis (SNY) [2]
Schering AG (SHR)		Shire plc (SHPGY)
Wyeth (WYE)		SuperGen, Inc. (SUPG)
		Wyeth (WYE)
Total Companies = 12	Total Companies = 7	Total Companies = 13

Notes:

1. Some drug candidates are filed jointly by two companies.
2. Companies with multiple drug candidates in the same month are shown in **bold type** with the number of drug candidates in brackets [].
3. Click the company name to view all NDA (New Drug Approval) Filed drug candidates for the company in [Revere Research](#).

3. Expected PDUFA Dates by Sector*

March	April	May
*Healthcare  Biopharmaceuticals [10]  Cardiovascular System [1]  Digestive System [2]  Hematology [1]  Infectious Diseases [1]  Musculoskeletal System [1]  Neurology [2]  Obstetrics/Gynecology [1]  Oncology [1]	*Healthcare  Biopharmaceuticals [8]  Digestive System/Surgery [1]  Endocrinology/Metabolism [2]  Neurology [2]  Oncology [1]  Respiratory System [1]  Toxicology [1]	*Healthcare  Biopharmaceuticals [10]  Cardiovascular System [1]  Dermatology [1]  Endocrinology/Metabolism [1]  Hematology [1]  Infectious Diseases [2]  Neurology [1]  Pain Management [1]  Toxicology [1]  Urology [1]
Total PDUFA Dates = 10	Total PDUFA Dates = 8	Total PDUFA Dates = 10

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

4. March 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?
Salix Pharmaceuticals Ltd (SLXP)	INKP-102 (Sodium Phosphate Purgative Tablet)	Cleansing Of Colon Prior To Colonoscopy	3/1/2006	Hyperosmotic Agents	Yes	**Yes—Colyte (SWTZY), LoSoPrep/ LiquiPrep (EZEM)	No
Bristol Myers Squibb Co. (BMY) / ImClone Systems Incorporated (IMCL)	Erbix (Cetuximab)	Recurrent/ Metastatic Head & Neck Cancer; Locally Advanced Head & Neck Cancer In Combination With Radiation	3/2/2006	Monoclonal Antibodies	Yes	Yes—Only Drug Candidate with This PMOA for This Indication	No (BMY) / Yes (IMCL)
Amgen, Inc. (AMGN)	Aranesp (Darbepoetin Alfa)	Once Every 3 Weeks Dosing For The Treatment Of Chemotherapy Induced Anemia	<i>3/6/2006</i>	Recombinant Human Erythropoietins	Yes	No—Multiple	No
NPS Pharmaceuticals, Inc. (NPSP)	Preos (Human Parathyroid Hormone)	Reduce Fracture Rates In Women With Osteoporosis	3/10/2006	Parathyroid Hormone	Yes	Yes—Forteo (LLY)	No
Cubist Pharmaceuticals (CBST)	Intravenous Cubicin (Daptomycin)	Bacteremia With Known Or Suspected Endocarditis Caused By Staphylococcus aureus	3/24/2006	Lipopeptides	Yes	Yes—Only Drug Candidate with This PMOA for This Indication	Yes
Encysive Pharmaceuticals, Inc. (ENCY)	Thelin (Sitaxsentan)	Pulmonary Arterial Hypertension (PAH)	3/24/2006	Endothelin Receptor Antagonists	No	Yes—Ambrisentan (MYOG)	Yes
Schering AG (SHR)	YAZ (Drospirenone/Ethinyl Estradiol)	Premenstrual Dysphoric Disorder (PMDD)	<i>3/24/2006</i>	Estrogens/ Progestins	Yes	Yes—Only Drug Candidate with This PMOA for This Indication	No
Santarus, Inc. (SNTS)	Zegerid Chewable Tablet (Omeprazole)	GERD, Erosive Esophagitis (EE), Duodenal Ulcer, Gastric Ulcers, Prevention of Upper GI Bleeding in Critically Ill Patients	3/27/2006	Proton Pump Inhibitors	Yes	No—Multiple	Yes
Biogen Idec Inc (BIIB) / Elan Corporation, plc (ELN)	Tysabri (Natalizumab)	Relapsing Forms Of Multiple Sclerosis	<i>3/27/2006</i>	Alpha 4 Integrin Inhibitors	No	Yes—Only Drug Candidate with This PMOA for This Indication	No
Wyeth (WYE)	Librel (Levonorgestrel/ Ethinyl Estradiol)	Continuous Oral Contraceptive	<i>March 2006</i>	Estrogens/ Progestins	Yes	No—Multiple	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.

* SLXP's NRL944 and Visicol are also indicated for Cleansing of Colon Prior to Colonoscopy.

5. April 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?
Discovery Laboratories (DSCO)	Surfaxin (Lucinactant)	Prevention Of Respiratory Distress Syndrome In Premature Infants (RDS)	4/05/2006	Surfactants	Yes	No—Multiple	Yes
Alkermes, Inc. (ALKS) / Cephalon, Inc. (CEPH)	Medisorb Vivitrex (Naltrexone)	Alcohol Dependence	<i>4/17/2006</i>	Opioid Antagonists	Yes	Yes—ReVia (BRL)	Yes (ALKS) / No (CEPH)
Cephalon, Inc. (CEPH)	Nuvigil (Armodafinil)	Excessive Sleepiness Associated with Narcolepsy, Shift Work Sleep Disorder, and Obstructive Sleep Apnea/Hypopnea Syndrome	4/28/2006	Alpha Adrenergic Receptor Agonists	Yes	Yes—Only Drug Candidate with This PMOA for This Indication	No
Genzyme Corporation (GENZ)	Myozyme (Alpha-Glucosidase)	Pompe Disease	4/28/2006	Enzyme Replacement Therapy	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 Aged 6 to 17	<i>April 2006</i>	Alpha Adrenergic Receptor Agonists	Yes	Yes—SPD503/SPD465 (SHPGY)	No
Pfizer Inc. (PFE)	Genotropin (Recombinant Human Growth Hormone)	Short Stature And Growth Problems Associated With Turner's Syndrome	<i>April 2006</i>	Growth Hormones	Yes	No—Multiple	No
Salix Pharmaceuticals Ltd (SLXP)	NRL944	Bowel Cleansing Prior To Colonoscopy, Intestinal Surgery And Barium Enema X-Ray Examinations	<i>April 2006</i>	Hyperosmotic Agents	Yes	**Yes—Colyte (SWTZY), LoSoPrep/ LiquiPrep (EZEM)	No
Sanofi-aventis (ADR) (SNY)	Taxotere (Docetaxel)	Advanced Gastric Cancer (Stomach Cancer)	<i>April 2006</i>	Antimicrotubule Agents	Yes	Yes—Only Drug Candidate with This PMOA for This Indication	No

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**SLXP's INKP-102 and Visicol are also indicated for Cleansing of Colon Prior to Colonoscopy.

6. May 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?
DOV Pharmaceutical, Inc. (DOVP) / Neurocrine Biosciences, Inc. (NBIX) / Pfizer Inc. (PFE)	Indiplon Immediate Release Capsule	Primary (Chronic) And Transient Insomnia	5/15/2006	Gamma-Aminobutyric Acid (GABA) Receptor Agonists	Yes	No—Multiple	Yes (DOVP) / Yes (NBIX) / No (PFE)
MGi Pharma, Inc. (MOGN) / SuperGen, Inc. (SUPG)	Dacogen (Decitabine)	Myelodysplastic Syndrome (MDS)	5/15/2006	Pyrimidine Analogs	Yes	Yes—Vidaza (PHRM)	No
Bristol Myers Squibb Co. (BMY) / sanofi-aventis (ADR) (SNY)	Plavix (Clopidogrel Bisulfate)	Acute ST-Segment Elevation Myocardial Infarction	<i>5/18/2006</i>	Adenosine Diphosphate (ADP) Inhibitors	Yes	Yes—Only Drug Candidate with This PMOA for This Indication	No
King Pharmaceuticals (KG) / Wyeth (WYE)	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)	Yes	Yes—Only Drug Candidate with This PMOA for This Indication	No
Merck & Co., Inc. (MRK)	Zostavax	Herpes Zoster (Shingles) Vaccine, , Prevention Of Postherpetic Neuralgia (PHN), Reduction Of Acute And Chronic Shingles-Associated Pain In Adults	5/25/2006	Herpes Zoster (Shingles) Vaccines	No	Yes—Only Drug Candidate with This PMOA for This Indication	No
Shire plc (SHPGY)	Elaprase (Idursulfase)	Hunter Syndrome (Mucopolysaccharidosis II)	5/25/2006	Enzyme Replacement Therapy	Yes	Yes—Only Drug Candidate with This PMOA for This Indication	No
Sanofi-aventis (SNY)	Pentacel	Combination Vaccine For Diphtheria, Tetanus, Pertussis, Polio, Haemophilus influenzae type b (Hib) In Children	<i>5/25/2006</i>	Bacterial/Viral Vaccines	Yes	Yes—Infanrix Hexa-HepB-IPV/Hib (GSK)	No
Johnson & Johnson (JNJ)	ALZA Ionsys (E-Trans Fentanyl)	Management Of Acute Post-Operative Pain	<i>5/29/2006</i>	Opioids	Yes	No—Multiple	No
CollaGenex Pharmaceutical, Inc (CGPI)	Oracea (Doxycycline Hyclate Modified Release)	Rosacea	5/31/2006	Tetracyclines	Yes	Yes—Only Drug Candidate with This PMOA for This Indication	No
Pfizer Inc. (PFE)	Champix (Varenicline)	Smoking Cessation	<i>May 2006</i>	Nicotinic Receptor Agonists	Yes	No—Multiple	No

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7. Price and Financial Info

Data as of February 27, 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 ?
March	Amgen, Inc. (AMGN)	75.48	92,388	15,439,464	4.45	0.19	5,255	20.17%	3.43%	●	YES
	Biogen Idec Inc. (BIIB)	50.10	17,004	2,982,030	2.41	0.00	851	-25.54%	-42.28%	●	YES
	Bristol Myers Squibb (BMY)	23.21	45,411	8,506,200	N/A	N/A	N/A	-6.90%	-23.64%	●	YES
	Cubist Pharmaceuticals (CBST)	23.04	1,238	515,534	73.56	9.95	102	108.13%	91.39%	●	YES
	Elan Corporation, (ELN)	13.95	5,982	7,680,800	354.08	119.36	1,090	-48.14%	-64.88%	●	YES
	Encysive Pharmaceutical (ENCY)	9.29	543	977,831	N/A	N/A	128	-20.12%	-36.86%	●	YES
	ImClone Systems (IMCL)	38.52	3,234	1,401,168	11.87	2.28	756	-15.53%	-32.27%	●	YES
	NPS Pharmaceuticals, (NPSP)	14.64	673	616,810	-6.90	N/A	259	-1.41%	-18.15%	●	YES
	Salix Pharmaceuticals (SLXP)	16.11	744	487,239	3.86	0.00	73	-2.36%	-19.10%	●	YES
	Santarus, Inc. (SNTS)	8.13	359	335,071	5.79	0.00	86	9.27%	-7.47%	●	NO
	Schering AG (SHR)	71.40	13,566	29,455	3.52	0.08	1,341	0.42%	-16.32%	●	NO
Wyeth (WYE)	50.05	67,180	4,397,600	N/A	N/A	N/A	23.28%	6.54%	●	YES	
April	Alkermes, Inc. (ALKS)	26.71	2,454	1,201,108	105.19	13.33	314	120.56%	103.82%	●	YES
	Cephalon, Inc. (CEPH)	80.68	4,687	2,529,301	7.37	2.77	484	60.08%	43.34%	●	YES
	Discovery Laboratories (DSCO)	7.67	412	491,036	11.49	0.30	50	24.72%	7.98%	●	YES
	Genzyme Corporation (GENZ)	70.00	18,076	2,275,028	3.28	0.00	1,089	21.25%	4.51%	●	YES
	Pfizer Inc. (PFE)	26.60	196,079	32,274,456	N/A	N/A	N/A	-0.97%	-17.71%	●	YES
	Salix Pharmaceuticals (SLXP)	16.11	744	487,239	3.86	0.00	73	-2.36%	-19.10%	●	YES
	sanofi-aventis (SNY)	43.51	116,184	1,958,345	2.19	N/A	N/A	9.40%	-7.34%	●	YES
May	Bristol Myers Squibb (BMY)	23.21	45,411	8,506,200	N/A	N/A	N/A	-6.90%	-23.37%	●	YES
	CollaGenex Pharmaceutical, (CGPI)	12.90	187	113,126	6.59	0.00	35	151.95%	135.48%	●	YES

DOV Pharmaceutical (DOVP)	19.23	444	498,586	N/A	N/A	109	24.39%	7.92%	●	NO
Johnson & Johnson (JNJ)	57.91	172,278	10,545,880	N/A	N/A	N/A	-12.55%	-29.02%	●	YES
King Pharmaceuticals (KG)	19.87	4,804	1,787,019	2.33	0.17	651	93.85%	77.38%	●	YES
Merck & Co., Inc. (MRK)	35.36	77,319	9,600,000	N/A	N/A	N/A	10.85%	-5.62%	●	YES
MGi Pharma, Inc. (MOGN)	17.98	1,393	1,013,054	N/A	N/A	N/A	-25.43%	-41.90%	●	YES
Neurocrine Biosciences, Inc. (NBIX)	69.10	2,571	584,916	6.60	0.15	273	69.61%	53.14%	●	YES
Pfizer Inc. (PFE)	26.60	196,079	32,274,456	N/A	N/A	N/A	-0.97%	-17.44%	●	YES
sanofi-aventis (SNY)	43.51	116,184	1,958,345	2.19	N/A	N/A	9.40%	-7.07%	●	YES
Shire plc (SHPGY)	47.57	7,895	1,094,975	4.32	0.00	663	40.16%	23.69%	●	YES
SuperGen, Inc. (SUPG)	5.24	270	339,395	4.20	N/A	51	3.56%	-12.91%	●	YES
Wyeth (WYE)	50.05	67,180	4,397,600	N/A	N/A	N/A	23.28%	6.81%	●	YES